federal register

TUESDAY, OCTOBER 3, 1978
PART VI

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

■

OCCUPATIONAL EXPOSURE TO ACRYLONITRILE (VINYL CYANIDE)

Final Standard

[4510-26]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to Acrylonitrile (Vinyl Cyanide)

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Final standard.

SUMMARY: By this final standard, the Occupational Safety and Health Administration (OSHA) sets the permissible limit of occupational exposure to acrylonitrile (AN) (also known as vinyl cyanide) at 2 parts acrylonitrile per million parts of air (2 ppm), as an 8-hour time-weighted average concentration (TWA), with a ceiling level of 10 ppm for any 15-minute period during the 8-hour day. In addition, the standard establishes an action level of 1 ppm as an 8-hour time-weighted average. The basis for this standard is OSHA's determination that laboratory and epidemiological data indicate that exposure to AN presents a cancer hazard to workers. Provision is also made for specific exemptions from the standard for the processing, handling, and use of acrylic and modacrylic fibers, ABS/SAN resins, nitrile barrier resins, and nitrile rubbers, when these materials are in the form of finished polymers, and certain other materials containing and/or made from AN. This standard is intended to minimize the potential for cancer among employees exposed to AN in the workplace. Employees protected by this standard work principally in the chemical and plastics industries. The standard requires that employee exposures be controlled to within the permissible exposure limits by engineering and work practices, supplemented by respiratory and other protective equipment in limited situations. The standard also requires the measurement of employee exposure, employee training, medical surveillance, and recordkeeping. The 2 ppm limit has been set because it will provide significant employee protection and is the lowest level feasible for most employers affected by the standard. The final standard supersedes the emergency temporary standard, which was issued on January 17, 1978.

EFFECTIVE DATE: This standard will become effective November 2, 1978. Startup dates: Installation of engineering controls shall be completed by November 2, 1980. Training programs shall be instituted by January 2, 1979. All other requirements of the standard shall be effective November 2, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Gail Brinkerhoff, Office of Compliance Programs, Occupational Safety and Health Administration, Third Street and Constitution Avenue NW., Room N-3112, Washington, D.C. 20210, telephone 202-523-8034.

For additional copies of this regulation, contact:

OSHA Office of Publications, U.S. Department of Labor, Room N-3423, Washington, D.C. 20210, telephone 202-523-8677.

SUPPLEMENTARY INFORMATION:

I. Background

Physical Properties, Manufacture, and Use of Acrylonitrile

Acrylonitrile ($CH_2=CHCN$; CAS #000107131) (AN) is a widely used chemical intermediate in the manufacture of acrylic fibers, synthetic rubbers, and plastics. Its use in the manufacture of a number of acrylic fibers and copolymer resins accounts for most of the 1.5 billion pounds of AN produced annually in the United States. AN is a clear, colorless (when pure), or yellowish liquid with a characteristic odor at relatively high concentrations and a molecular weight of 53.06. It is very reactive and polymerizes violently in the presence of strong bases. Pure AN is subject to self-polymerization with rapid pressure development (the commercial product is inhibited and not subject to this reaction), AN is a volatile (vapor pressure 83 mm Hg at 68° F), flammable liquid with a flash point of 30° F (open cup), is easily ignited and may release cyanide gases when burned, especially where the supply of oxygen is limited. Its vapors are heavier than air, and when diffused over a considerable range of concentrations in air (3-17 percent by volume), are highly explosive. Synonyms for AN include acrylon, carbacryl, cyanoethylene, fumigrain, 2-propenenitrile, VCN, ventox, and vinyl cyanide.

AN is produced almost exclusively by the ammoxidation of propylene in the presence of a catalyst. Current producers of AN in the United States are American Cyanamid, duPont, Monsanto, and Vistron (SOHIO).

The major use of AN is in the production of acrylic and modacrylic fibers by copolymerization with other monomers such as methyl acrylate, methyl methacrylate, styrene, vinyl acetate, vinyl bromide, vinyl chloride, or vinylidene chloride, individually or in combination. Acrylic fibers are, by definition of the Federal Trade Commission, fibers composed of at least 85 percent (by weight) acrylonitrile units. Fibers composed of at least 35 percent but less than 85 percent acrylonitrile units are referred to as "modacrylic fibers." AN-based synthetic fibers are used in the manufacture of apparel, carpeting, blankets, draperies, and upholstery. Major producers of acrylic and modacrylic fibers include American Cyanamid Co., Dow Badische Co., E. I. du Pont de Nemours & Co., Tennessee Eastman Co., and Monsanto Co. In 1976, acrylic and modacrylic fiber production comprised 50 percent of the total AN consumption in the United States.

The manufacture of acrylic fibers involves four basic steps. First, the acrylonitrile must be polymerized; second, the polymer must be dissolved in a solvent to form a viscous solution which can be forced through a spinnerette (spinning head); third, the polymer must be spun into fiber; and, fourth, the fibers must be processed, crimped, cut, dried, and baled. The production of acrylic fibers is done by either wet-spinning or dry-spinning. Both methods require that the polymer be dissolved or suspended in a suitable solvent. The solvent used may vary from company to company.

The dissolved or suspended polymer is extruded through the spinnerette, or spinning head, which is a metal plate with thousands of tiny holes in it. The polymer is extruded through the holes in the spinnerette and coagulated to form the fibers. The solvent and excess, or residual AN monomer are then removed from the fibers. In dry-spinning, the solvent is removed by hot gases. In wet-spinning, on the other hand, the fibers are extruded into another liquid bath, which serves to remove the solvent. For both types of spinning, the resulting fibers must be stretched to increase their strength, and then crimped to provide the desired texture and facilitate processing on textile machinery. Where the wet spinning process is used, the fibers are drawn from the coagulation bath through various warm water baths to remove any remaining solvent before they are drawn through the hot water stretching bath. It is during this stage of the wet-spinning process, between the coagulation bath and the hot water stretch, that potential employee exposure to acrylonitrile is greatest, since residual (i.e., unreacted) AN monomer which remains in the fiber is being driven off along with the solvent.

Residual AN levels for all finished acrylic fibers are usually well below 20 parts per million by weight, and the fibers do not readily release their residual AN. The polymer structures

from which acrylic fibers are produced contain acrylonitrile links in the form of a long coil. In the dry, cool state, these structures are dense or tightly coiled. At the glass transition temperature (i.e., the temperature at which the molecular structure opens up; approximately 180° C dry and approximately 80° C in water) the polymer uncoils, allowing the release of anything being held in that coil (e.g., residual monomer or water). Since the fiber has a great affinity for water and water tends to extract the residual AN, removal of residual AN at the wet glass-transition temperature is fairly complete. As the fibers are normally washed at this temperature during processing, little residual AN remains in the final product. Because polymers such as acrylic fibers, which contain long sequences of AN units, tend to cyclize (i.e., form chains of six-sided rings) at temperatures above 250° C instead of reverting to their component monomers, little, if any, acrylonitrile exposure results from decomposition of the fibers.

Other major uses of AN include the manufacture of resins, plastics, nitrile elastomers (rubbers and latexes), and polymer polyols as well as in the production of other chemicals, such as adiponitrile and acrylamide.

Acrylonitrile-based resins and plastics are produced from three monomers, acrylonitrile, butadiene, and styrene, and have a wide range of uses. They can be processed in many different ways into a variety of fabricated products. In the manufacture of ABS resins, butadiene and styrene are first copolymerized to form a "spine" or base polymer. Styrene and acrylonitrile chains are then grafted onto this base polymer. In a separate operation, acrylonitrile and styrene are copolymerized to form a resin, and this resin is then mixed with the grafted polymer to produce a latex. The latex is then flocculated (formed into clumps), filtered, washed, and dried.

Potential exposure to acrylonitrile occurs at many points during the ABS resin manufacturing process. This operation involves the conveyance of AN monomer from storage tanks to various process areas and necessarily includes many valves, gaskets, pipes, sampling points, and other areas where AN may be released, either from leaks in the equipment or from the opening of the system, as during sampling. In addition, the blending, flocculation, and drying areas are potential areas of exposure, because the mechanical and heat processing of the polymer latex causes residual AN in the polymer to be released. Since suspension and solution polymerization processes involving latex or slurry usually result in relatively high levels of residual AN, the processing of the polymer can result in a substantial release of AN.

The manufacture of nitrile rubber from acrylonitrile and butadiene also involves the processing of latex and slurry, and therefore, includes similar areas of potential exposure to AN monomer. In addition, the polymerization process for the production of nitrile rubber results in higher employee exposures (both actual and potential), since the polymerization process is not complete when the contents of the reactor, called the "charge," are transferred to the blowdown tank. The latex, therefore, contains a considerable amount of residual monomer when it is moved from the blowdown tank to the distillation tank for "steam-stripping" to remove residual monomer. Even after stripping, the latex contains enough AN monomer to cause high exposures in the processing areas, and subsequently in the washing and drying areas.

Besides the major uses discussed above, AN is also used in the manufacture of latexes for use in paints, adhesives, and industrial coatings, as well as in the manufacture of chemical intermediates for dyes and other products.

It is estimated that 5,130 employees are currently exposed to acrylonitrile; of these 1,050 are in AN production, 1,250 in acrylic fiber production, 850 in nitrile elastomer manufacture, 1,900 in ABS/SAN resin manufacture, and 80 in polyol production (Ex. 15).

II. Pertinent Legal Authority

The primary purpose of the Act is to assure, so far as possible, safe and healthful working conditions for every working man and woman. One means prescribed by Congress to achieve this goal is the authority vested in the Secretary of Labor to set mandatory safety and health standards.

Occupational safety and health standards provide notice of the requisite conduct or exposure level and provide a basis for assuring the existence of safe and healthful workplaces. The Act provides that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such a standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws (Section 6(b)(5)).

Sections 2(b) (5) and (6), 20, 21, and 24 of the Act reflect Congress recognition that conclusive medical or scientific evidence, including causative factors, epidemiological studies or dose-response data, may not exist for many toxic materials or harmful physical agents. Nevertheless, standards cannot be postponed because definitive medical or scientific evidence is not currently available. Indeed, standards need only be supported by the best available evidence. The legislative history makes it clear that "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Committee on Education and Labor, Report No. 91-1291, 91st Cong., 2d session, p. 18 (1970). This congressional judgment is supported by the courts which have reviewed standards promulgated under the Act. In sustaining the standard for occupational exposure to vinyl chloride (29 CFR 1910.1017), the U.S. Court of Appeals for the Second Circuit stated that "it remains the duty of the Secretary to act to protect the working man, and to act even in circumstances where existing methodology or research is deficient." *Society of the Plastics Industry, Inc.* v. *Occupational Safety and Health Administration*, 509 F. 2d 1301 (2d Cir., 1975), cert. denied, 421 U.S. 992 (1975).

A similar rationale was applied by the U.S. Court of Appeals for the District of Columbia Circuit in reviewing the standard for occupational exposure to asbestos (29 CFR 1910.1001). The Court stated that:

> Some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision-making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual judgments.

Industrial Union Department, AFL-CIO v. *Hodgson*, 499 F. 2d 467, 474 (C.A.D.C. 1974).

In setting standards, the Secretary is expressly required to consider the feasibility of the proposed standards. Senate Committee on Labor and Public Welfare, S. Rept. No. 91-1282, 91st Cong., 2d sess., p. 58 (1970). Nevertheless, considerations of technological feasibility are not limited to devices already developed and in use. Standards may require improvements in existing technologies or require the development of new technology. *Society of the Plastics Industry, Inc.* v. *Occupational Safety and Health Administration, supra*, at 1309; *American Iron and Steel Institute* v. *OSHA*, No. 76-2358 (3d Cir., 3/28/78).

Where appropriate, the standards are required to include provisions for labels or other forms of warning to apprise employees of hazards, suitable protective equipment, control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and appropriate medical examinations. Moreover, where a standard prescribes medical examinations or other tests, they must be made available at no cost to the employees (Section 6(b)(7)). Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illnesses (Section 8(c)).

III. History of the Regulation

Prior to the issuance of the Emergency Temporary Standard (ETS) in 1978, occupational exposure to AN was limited by OSHA to an 8-hour time-weighted average of 20 ppm (or approximately 45 mg/m^3) as was found in table Z-1 of 29 CFR 1910.1000. The 20 ppm standard was not based on the carcinogenicity of AN, but was based on its high acute toxicity and its similarity to hydrogen cyanide.

In March 1977, the Manufacturing Chemists Association (MCA) informed OSHA of the interim results after 1 year of a planned 2-year study being conducted by Dow Chemical Co.'s laboratories on the chronic toxicity of ingestion of acrylonitrile by rats. Sacrifices of some of the animals after 1 year showed the development of various tumors, including central nervous system (CNS) and ear canal tumors, among the treated animals, but not among the controls. The tumors were found in animals exposed to 100 and 300 ppm, respectively, in their drinking water. Later reports from MCA, in April 1977, indicated that similar tumors had been found in the lowest exposure group in the test, 35 ppm, and that findings after 1 year of a continuing 2-year study of inhalation of AN by rats noted "comparable" CNS tumors in animals inhaling 80 ppm AN.

In May 1977, E. I. du Pont de Nemours & Co., Inc. (du Pont) informed OSHA of the preliminary results of an epidemiological study demonstrating an excess of cancer among workers exposed to acrylonitrile in a du Pont textile fibers plant in Camden, S.C. Although du Pont stressed the preliminary nature of these findings, the company did state that when considered in light of the recent animal tests, "[they] raise serious suspicion that it [acrylonitrile] may be a human carcinogen."

On June 29, 1977, OSHA published a request for information on acrylonitrile in the Federal Register (42 FR 33043) and again on July 5, 1977 (42 FR 34326). In this document, OSHA discussed the new information that had been received from MCA and du Pont, and requested specific information on various issues relating to occupational exposure to AN. Interested persons were requested to furnish information by July 29, 1977.

OSHA received 25 replies to the request for information, many of which contained considerable data and technical details on the manufacture and use of acrylonitrile, areas of potential employee exposure, and other relevant material.

Shortly after OSHA's request for information appeared in the Federal Register, on July 1, 1977, the National Institute of Occupational Safety and Health (NIOSH), issued a "Current Intelligence Bulletin" on acrylonitrile, outlining the information received from MCA and du Pont, discussing the other toxic effects of AN exposure, and recommending interim industrial hygiene practices to be implemented in the workplace to help reduce occupational exposure to acrylonitrile.

On September 29, 1977, NIOSH provided recommendations for a revised standard for AN. A permissible exposure level of 4 ppm AN in air as determined by a 4-hour sample collected at a rate of 0.2 liter/minute was suggested. This recommendation was based on what NIOSH considered to be the analytical limits of the air measurement technique at that time.

A NIOSH communication dated December 7, 1977 said that

> (a)lthough the preliminary results of the du Pont epidemiologic study are inconclusive by themselves, * * * when viewed in light of the preliminary rat data the conclusion with regard to acrylonitrile is clear—the chemical must be viewed as a proven animal carcinogen and suspect human carcinogen. To do otherwise would be to place the health of exposed workers in jeopardy until more conclusive evidence ultimately surfaces.

On January 17, 1978, after a review of the available data, OSHA issued an emergency temporary standard (ETS) for occupational exposure to acrylonitrile (43 FR 2586). As discussed more fully in the preamble to the ETS, the emergency standard was based upon the Assistant Secretary's determination that exposure to AN posed a grave danger to humans. The ETS established permissible exposure limits of 2 ppm as an 8-hour time weighted average, with a ceiling limit of 10 ppm as averaged over any 15-minute period during the 8-hour workshift. The ETS allowed considerable flexibility in control techniques, permitting the employer to implement any practicable combination of engineering, work practices, and respiratory protective devices during the 6-month effective period of the ETS.

In the same issue of the Federal Register, OSHA published a proposed permanent standard for occupational exposure to AN (43 FR 2608). The proposal contained additional provisions which OSHA believed to be more appropriate to a permanent regulation than those presented in the ETS. In addition, the proposal set forth three alternative sets of permissible exposure limits for consideration: 2 ppm TWA with a 10 ppm ceiling; 1 ppm TWA with a 5 ppm ceiling; and 0.2 ppm TWA with a 1 ppm ceiling. A period for receipt of written comments was established, to extend through February 21, 1978, to consider the proposed permanent standard.

In the preamble to the proposal, OSHA requested public comments, information, and evidence on all issues raised in the proposal.

On February 24, 1978 (43 FR 7669), OSHA published a notice of availability of an economic and technological impact assessment which had been prepared for the Agency by Enviro Control, Inc., of Rockville, Md. (ECI). As noted in the preamble to the proposal, this assessment was developed in accordance with Executive Orders 11821 (39 FR 41501) and 11949 (42 FR 1017). The ECI document examined the three alternative sets of exposure limits contained in the proposed standard. The comment period was extended to March 21, 1978, for the receipt of written comments solely on the ECI report. In addition, participants at the hearing were given additional time to submit their testimony and documentary evidence on that report.

The informal rulemaking hearing was convened by Administrative Law Judge Randolph Mason on March 21, 1978, pursuant to notice and section 6(b)(3) of the Act (29 U.S.C. 655(b)(3)). The hearing lasted through April 4, 1978. Post-hearing submissions of data requested by parties at the hearing were received through April 19, 1978. Post-hearing comments and briefs were received through May 19, 1978.

The entire record, including over 160 exhibits and approximately 1,300 transcript pages and errata, was certified by the presiding administrative law judge on August 18, 1978, in accordance with 29 CFR 1911.17. Copies of materials in the record, as well as an index of the record, may be obtained from the OSHA Docket Office, Room S6212, U.S. Department of Labor, 3d Street and Constitution Avenue NW., Washington, D.C. 20210.

The final standard on occupational exposure to acrylonitrile is based on a full consideration of the entire record of this proceeding, including materials discussed or relied on in the ETS and proposal, the record of the informal

hearing, and all written comments and exhibits received.

IV. Health Effects of Exposure to Acrylonitrile

Information regarding the acute toxic effects of acrylonitrile (AN) on both animals and humans is extensive, and was discussed at length in the preamble to OSHA's Emergency Temporary Standard (ETS) for AN and will not be repeated here (42 FR 2586). While the toxic effects of AN have long been recognized, data demonstrating its carcinogenicity have only recently become available.

CARCINOGENICITY

Cancer is one of society's most dreaded diseases. It is generally an irreversible process whereby abnormal cells may invade and/or destroy surrounding tissue and if left untreated, culminates in the death of such tissue and ultimately in the death of the organism. Although progress has been made in the early detection of cancer, and in some cases its effective "cure", much remains to be learned about the mechanism of cancer induction and the various causative factors involved in carcinogenesis. However, in recent years research has demonstrated that exposure to certain chemicals in the environment and the workplace is among the important causes of cancer.

While cancer manifests itself in a variety of forms, certain characteristics are generally common to occupational cancer. One of these is the long latent period between initiation of the carcinogenic response and clinically visible evidence of the disease. Another characteristic is that once the initial carcinogenic events have been triggered, the disease continues to progress even in the absence of continued exposure.

Based upon a careful review of evidence contained in the record, OSHA concludes that acrylonitrile poses a carcinogenic risk to workers. This conclusion is derived from the results of experimental studies which have shown excess incidences of tumor formation in AN-exposed animals and is supplemented by indications of a cancer excess among workers exposed to AN. Moreover, AN has also been shown to be capable of inducing mutations (permanent, transmissible changes in the genetic material), an effect which has been observed for other cancer-causing chemicals.

OSHA's determination as to the carcinogenicity of AN is supported by the findings of other governmental agencies and scientific organizations. Based on the results of industry-sponsored animal studies, the National Cancer Institute's carcinogenicity testing program has "recognized acrylonitrile as carcinogenic to experimental animals and has discontinued its plans to further test the compound as a potential carcinogen" (Ex. 21).

The International Agency for Cancer Research (IARC) of the World Health Organization has recently stated in a draft report:

> * * * the data [from interim animal studies] indicate that acrylonitrile is carcinogenic to rats, producing tumours of the forestomach, brain and Zymbal glands. Acrylonitrile is also embryotoxic, teratogenic [causes fetal malformations], and mutagenic [causes mutations] (Ex. 23).

The IARC went on to say:

> * * * combined evidence from human and experimental data, plus that of the positive mutagenic activity of acrylonitrile, indicate that while confirmatory evidence from experimental animals and humans is desirable, acrylonitrile should be regarded as if it were carcinogenic to humans (Ex. 23).

In testimony prepared for this rulemaking, the National Institute for Occupational Safety and Health (NIOSH) concluded:

> AN has been shown to be a chemical carcinogen on the basis of animal experiments. The interim results which we have reviewed are significant (Ex. 42).

NIOSH also stated:

> The results from the experimental animal studies have been reinforced by the du Pont mortality study of workers exposed to AN * * * Though incomplete, the results strongly suggest that AN is carcinogenic in man (Ex. 42).

The Food and Drug Administration (FDA), in banning the use of plastic containers made with acrylonitrile concluded that:

> * * * acrylonitrile is a frank teratogen in the rat, a tumorigen [an agent capable of causing tumors] and probale [sic] carcinogen in the rat, a possible carcinogen in man and a mutagen in several test systems (Ex. 6:(174)).

Finally, several industry participants also submitted statements to the record regarding the carcinogenicity of AN. Monsanto stated that:

> "* * * it is prudent to reduce the TLV [threshold limit value] since it has been established that AN is an experimental carcinogen" (Ex. 11:(27)).

Du Pont, in referring to the preliminary results of their epidemiologic study, said:

> * * * these findings, when considered together with the results of the animal tests which were reported previously, raise a serious suspicion that it may be a human carcinogen (Ex. 14:(71)).

The determination that AN is a cancer-causing chemical was the basis for OSHA's issuance of the ETS for AN early this year. The evidence on which this finding was based included the results of experimental animal studies and human epidemiology. This evidence was the focus of much testimony during the subsequent public hearing for this rulemaking. The major scientific issues raised relevant to this subject are summarized below.

1. *Evidence in animals.* The use of animal data as a predictor of human response to environmental carcinogens is widely accepted in the scientific community (cf. Tr. 565; 614; Exs. 5:(14-22); 40; 42; 98; 109; 110). OSHA has relied upon experimental evidence in this manner in several previous rulemakings on carcinogens. Available animal data on acrylonitrile clearly indicates the potential for carcinogenic effects in humans.

In March 1977 the Dow Chemical Co. laboratories informed OSHA of the results after 12 months of a 2-year rat ingestion study of acrylonitrile (Ex. 5:(3)). This investigation (hereafter referred to as the "Drinking Water" study), sponsored by the Manufacturing Chemists Association (MCA), was designed to assess the chronic toxicity and potential carcinogenicity of AN. This report showed an increased incidence of tumors of the stomach, central nervous system (CNS) and Zymbal gland of the ear canal in rats receiving 100 and 300 ppm acrylonitrile in their drinking water and sacrificed after 12 months. A letter from MCA dated April 11, 1977 supplemented this information with notice of a subsequent report from Dow which stated:

> * * * at the 12-month interim sacrifice on 10 rats per sex per dose level gross and microscopic pathologic changes of a tumorous nature were detected with greater frequency in the 100 and 300 ppm AN groups compared to the 35 ppm AN and control groups; and tumors in the stomach, central nervous system (CNS) and Zymbal gland of the ear canal region were found with increased frequency in rats ingesting 100 or 300 ppm AN and were considered treatment-related (Ex. 5:(1)).

It was noted that on April 7, the investigator had reported that the same type of CNS tumors as seen in the groups of rats receiving doses of 100 and 300 ppm had been found in two rats at 35 ppm, the lowest ingestion level under test (Ex. 5:(1)).

The CNS tumors seen at all test levels of this study were microglioma, primarily of the brain and one of the spinal cord.

In his review of the results of this study, Dr. Cipriano Cueto, Jr., an eminent toxicologist and scientist who is currently Acting Chief of the Toxicology Branch of the Carcinogenesis Testing Program in the Division of Cancer Cause and Prevention at the National Cancer Institute (NCI) and Chairman of both NCI's Experimental Design Group and Data Evaluation Group, said:

> The study is appropriately designed to determine the potential carcinogenicity of

acrylonitrile (AN) as well as to assess other possible chronic toxic effects of the compound in rats (Ex. 21).

Dr. Cueto noted that the results of histopathologic examination of tissues of the sacrificed animals indicate that a trend of specific tumor induction appears to already be developing, and added:

The presence and incidence of microgliomas, although not statistically significant at this time, are considered, because of their rare spontaneous occurrence, as biologically highly important in implicating acrylonitrile as carcinogenic to Sprague-Dawley rats of both sexes.

The incidence of squamous cell papillomas observed in the stomach of both female and male rats receiving acrylonitrile are statistically significant as compared to controls. Further support of the possible tumorigenic effect of acrylonitrile is the fact that those lesions also are spontaneously rare in rats.

Based on the findings described above, the National Cancer Institute, Carcinogenesis Testing Program has recognized acrylonitrile as carcinogenic to experimental animals and has discontinued its plans to further test the compound as a potential carcinogen (Ex. 21; Tr. 213; 258-261).

During testimony at OSHA's hearing, Dr. Cueto stated that the MCA 12-month interim data had appeared at approximately the time that the NCI had been involved in conducting its prechronic studies as a precursor to the then-proposed long-term chronic studies on acrylonitrile, the purpose of which was to assay for its carcinogenic potential. After an evaluation of the MCA data, the decision was made to discontinue those studies (Ex. 21; Tr. 213-214). Dr. Cueto said that this decision had been made because the NCI considered the MCA studies to be well-designed for the purposes of cardinogen bioassay and had already shown the substance to be a carcinogen on the basis of the interim test results as reported after 1 year (Tr. 258-261). Asked if it was the normal policy of the National Cancer Institute to draw conclusions on carcinogenicity based on interim results from animal bioassays, Ceuto responded: "* * * Yes, we do make these evaluations on shorter terms" (Tr. 260-261). When asked if he would have continued the MCA studies after 1 year if he had been running them, to see what the final results were, he replied that he, too, would have continued the tests, but added:

* * * That doesn't mean that the data after 12 months was not [sic] the type of data that I would sit on. And that's exactly what they did also, they didn't sit on it. And the reason they didn't sit on it is because they know that that's important data, in terms of risk (Tr. 262).

Dr. Cueto went on to say that the International Agency for Cancer Research (IARC) of the World Health Organization, during their most recent meeting in Lyons, France, had evaluated the same and other data available to them relevant to the issue of AN carcinogenicity, and had supported the NCI finding (Tr. 213). In their draft report, the IARC stated:

Acrylonitrile was tested in rats by oral administration and inhalation exposure. Although full results of the study were not available, the data indicated that acrylonitrile is carcinogenic to rats, producing tumors of the forestomach, brain, and zymbal glands. Acrylonitrile is also embryotoxic, teratogenic, and mutagenic (Tr. 213; Exs. 23; 24).

Another 2-year study sponsored by MCA and being conducted by Dow involves the inhalation exposure of rats to acrylonitrile. In this study, an unreported number of male and female rats have been exposed to 0, 20, and 80 ppm acrylonitrile for 6 hours per day, 5 days per week (Ex. 5:(1)). After the first year of the study, 13 rats per sex, per dose level were sacrificed, and the following preliminary results were reported by MCA:

(1) Microscopic evaluation of tissues from these rats exposed to 80 ppm AN for 1 year revealed the presence of tumors in the CNS of three animals;

(2) These (CNS) tumors are comparable to those reported in the ingestion study;

(3) Upon gross examination of the other rats from the 2-year inhalation study, an increased incidence of ear canal tumors and mammary region masses was detected at the 80 ppm AN level;

(4) In the animals exposed to 20 ppm AN there was an apparent increase in the subcutaneous masses of the mammary region; and

(5) No ear canal or CNS tumors were observed at this (20 ppm) dose level (Ex. 5:(1)).

In a more recent letter to the Assistant Secretary dated February 22, 1978, notification was given by MCA of the termination of this 2-year inhalation study and their receipt of a report from Dow giving information on this study. In this report Dow stated that:

Exposures of Sprague-Dawley rats to 80 or 20 ppm acrylonitrile were terminated on January 18, 1978.

Findings available to date from this study include:

(a) The preliminary findings of the tumors from gross pathologic examination of all animals, and;

(b) The microscopic pathologic findings in the central nervous system of a majority of the animals exposed to acrylonitrile. Microscopic examination of central nervous system tissue from control animals has not as yet been completed (Ex. 14:(64)).

Although all of the data had not yet been accumulated, Dow noted that:

Based on the gross pathologic examination of the rats exposed to 80 ppm acrylonitrile, there was an increase in the incidence of tumors of the ear canal gland in males and females, of the gastrointestinal tract in males and in the subcutaneous mammary region in females. Preliminary results of the microscopic examination of the central nervous system tissue from the rats exposed to 80 ppm confirmed the presence of brain tumors previously reported.

In addition, Dow stated:

Based on the gross pathologic examination of rats exposed to 20 ppm acrylonitrile there was an increase in the incidence of subcutaneous mammary region tumors in the female rats. Microscopic examination of the central nervous system tissue from the rats exposed to 20 ppm has revealed a higher incidence of brain tumors when compared to historic control data (Ex. 14:(64)).

In their evaluation of this information, Dow said:

Interpretation of data from this study must await the complete evaluation of the findings of the microscopic examination of all tissues from the control and acrylonitrile exposed animals (EX. 14:(64)).

Dr. Robert Squire, a pathologist/oncologist, who was formerly Associate Chief of the Experimental Pathology Branch and head of its Tumor Pathology Section in the carcinogenesis program as well as former Acting Director of the NCI carcinogen bioassay program, also reviewed the MCA data on acrylonitrile. In his prepared testimony, Dr. Squire stated that:

The conclusions can clearly be drawn that acrylonitrile is carcinogenic under the conditions of this experiment. There is definite indication that malignant neoplasms of the central nervous system were induced at all dose levels by the oral route and at the 80 ppm level in the inhalation study. Benign gastric neoplasms, and preneoplastic epithelial alterations in the stomach are also clearly treatment related.

Although the malignant ear neoplasms and the mammary neoplasms occurred with low incidence in the initial report of interim observations, their numbers still exceeded that in the controls, and that expected according to historic observations. A tentative conclusion must be that these are also treatment related.

Statistical analysis is less than conclusive when dealing with small numbers of animals and preliminary observations, and in fact, not essential when interpreting the significance of these unusual findings (Ex. 28).

Most importantly, Dr. Squire stated that since the time his statement had been submitted he had had the opportunity to examine selected slides from the drinking water study, and had found that the tumors seen had been qualitatively distinctly different from those seen in control rats of any strain. He commented that this evidence was almost as compelling as the numbers that were seen (Tr. 542).

Three other board certified pathologists, Drs. David Groth, Choudari Kommineni, and Ralph Yodaiken, all currently with NIOSH, also examined the rat-tissue sections prepared by Dow and reviewed the results of the MCA studies. Their reports were transmitted to OSHA in a NIOSH memorandum dated December 7, 1977. In his report, Dr. Yodaiken stated:

Despite the small number of animals (10 per group) examined thus far, the results are both statistically and biologically significant. Acrylonitrile appears to be responsible for malignant change occurring in the central nervous system; the ceruminous glands of the ear canal, far in excess of any spontaneous tumor incidence; and possibly for the early appearance of mammary gland tumors. The papillomata of the stomach must be considered both directly related to the ingestion of the acrylonitrile and premalignant (Ex. 5:(13)).

In their report, Drs. Groth and Kommineni conclude that "acrylonitrile is a carcinogen in rats" (Ex. 5:(13)).

Several industry participants contend that the MCA data constitute interim data which are "too incomplete to form the basis for any conclusion" and that "the complete analysis of results should be forthcoming within the near future" (Exs. 146; 148; 155). While MCA has indicated that this data will eventually be made available, there has been no clear indication as to when this data can be expected to be fully analyzed and reported. In this regard it must be noted that at the public hearing, Mr. Grover Wrenn, Director of Health Standards Programs for OSHA stated:

We have had for some time an indication of the projected time frames of the Dow study being done for MCA. It is my understanding that the periods of exposure are done, the pathology is being performed, and I think it is reasonable to anticipate that the reports will be available during the period of this rulemaking, although I don't have an indication of a precise report date (Tr. 36).

At the hearing, Dr. Kenneth Burgess, of the styrene plastics division of Dow Chemical, was asked if he could provide any information on the status of the final results of the MCA study. Dr. Burgess replied that while he had not been involved with that study in the last 6 months, he did know that the animals had been sacrificed some time in January and work had begun on the pathology. Dr. Burgess noted that "* * * it is a very long and tedious process".

All I can say is that I am sure they are very diligently pursuing it. As to time, I am not even sure that Dr. Gehring or Dr. Norris would be able to give us the exact time. It will be, I am sure, some months (Tr. 911).

Vistron noted later that they had been advised that there would be no additional interim report of the MCA findings, that all the animals had been sacrificed and that the "final results will be out sometime this summer" (Tr. 1096).

As no testimony was presented by MCA at the hearing and since no industry witness was available to specifically address this issue, OSHA made a formal request at the hearing that industry make an effort to obtain that data (Tr. 1054). OSHA made further inquiry into the availability of this data informally with MCA subsequent to the hearing. This, too, yielded no additional information. As of this writing, no final report has been received by OSHA.

Although the results of the longer term portion of these studies are clearly of interest and importance, the interim data cannot be ignored. Several highly qualified scientists of wide experience in oncology, pathology, toxicology and cancer research have reviewed the results of MCA's interim report of their drinking water study and have stated that this data is itself of great significance, particularly in the context of all other available data. Furthermore, as previously noted, these scientists have concluded, as have some industry participants, that AN is a carcinogen.

Dr. Squire stated during testimony, that while he has been generally opposed to analysis of interim observations in animal experiments, he has found that:

* * * Observations in this study are well out of line with expected observations even after a lifetime, much less at 1 year of age, and in my view they provide very convincing evidence of the carcinogenic effect (Tr. 543).

This point was discussed in greater detail by Dr. Squire in his prehearing statement:

Interim or preliminary data is not customarily considered appropriate for carcinogenic evaluation, since the more common tumors which occur with variable incidence in test animals may produce false positive trends which are not supported by final observations.

However, particularly in the case of brain and stomach tumors of this type, immediate concern is warranted by the interim observations. These are rare tumors which do not occur in any rat strain at any age at incidences comparable to those observed in this experiment. Experience in laboratory animal oncology, plus the recent observations of additional tumors in remaining treated animals indicates that the evidence for carcinogenic effect will undoubtedly become more conclusive as the experiments progress (Ex. 28).

Industry has questioned the finding of biological (rather than statistical) significance of the MCA data based on the rare occurrence of the tumors seen (Ex. 146). During testimony, Dr. Squire said that spontaneous tumors of the brain and stomach are rare in all strains of rats at any age, having a spontaneous incidence of 1 percent or less (cf. Exs. 21; 35; 42; 45-51; Trs. 226-237; 541; 551-553; 562). Dr. Squire noted that:

* * * The power of the statistical test is very small when dealing with animal groups of this size.* * * There are other statistical tools for looking at this type of data (Tr. 541-542).

Statistical analysis supportive of this point was submitted to the record by Dr. Cueto. He determined what the probability was that the observation of a heretofore "rare" tumor was, in actuality, due to chance. Dr. Cueto said that as regards a rare tumor (i.e., one which appears at a site which does not very commonly respond to chemicals, does not have a history of a significant incidence of spontaneous tumors, and therefore, cannot be adequately supported by the most usually relied upon statistical analyses), "one must narrow the focus" and use more finely adapted calculations which can show whether this rare tumor was likely to be due to chance or to other causes. He said that such calculation had shown that the incidence of CNS tumors in the males (2 animals with tumors out of 10 examined in the drinking water study) at the 100 parts per million concentration gave a P value of 0.0003, "* * * a very small probability (3 in 10,000) that this is due only to chance" (Tr. 236-239; Ex. 23).

Other significant research into the carcinogenicity of AN includes studies recently reported in a European journal (Ex. 13). This work was conducted by Professor Cesare Maltoni, a noted research scientist currently with the Institute of Oncology and Tumor Centre in Bologne, Italy. The project, supported by the European Study Group for AN, includes experiments designed to study the long-term effects of AN on rats. Two studies designed to test the chronic effects of AN are discussed: One is an inhalation study, while the other involves the administration of AN by gavage (stomach tube).

In the inhalation study, 30 Sprague-Dawley rats of each sex were grouped according to treatment and exposed to either 0, 5, 10, 20, or 40 ppm of AN, 4 hours a day, 5 days a week for 52 weeks. The rats then went without treatment until their natural deaths, at which time complete autopsy was performed on all animals. Several tumor types were observed in this experiment. Those reported with greatest frequency were mammary tumors, Zymbal gland carcinomas, forestomach papillomas, and acanthomas (squamous cell carcinomas), encephalic (brain) tumors, skin carcinomas, and uterine carcinomas.

Dr. Harry Plotnick, a toxicologist and research pharmacologist testifying for NIOSH, also commented on the interim data from MCA. During testimony, he noted that the interim sacrifice protocol used by Dow in the drinking water study was a valid experimental design to look at the course of development of tumorogenesis (Tr. 690). He said that a study of this sort should be run for 18 months

or longer for completeness but that "if significant results arise before that time they still are significant no matter how long the study runs" (Tr. 691). This point is addressed further in a paper published in 1977 by Drs. Saffiotti and Page of the carcinogenesis program at the National Cancer Institute in which they state the policy of the Institute on the issue of timing and extent of reporting carcinogenesis bioassays. Drs. Saffiotti and Page state that:

> Delaying public notification of highly suspicious findings until a final, detailed report is published, may delay preventive actions that could protect exposed populations from unnecessary risks (Ex. 110).

OSHA agrees, and has therefore determined that despite their interim and preliminary nature, these data in conjunction with all other available data present clear and convincing evidence of the carcinogenicity of acrylonitrile.

Dr. Maltoni noted that the 3 encephalic tumors observed in this study were found in the animals treated at the highest doses (40 and 20 ppm).

In the gavage study, only one dose (5 mg/kg body weight) was administered to the AN-treated animals. Acrylonitrile in olive oil was given to 40 Sprague-Dawley rats of each sex and administed by stomach tube at the rate of once each day, 3 days/week for 52 weeks. Another groups of rats, consisting of 82 females and 77 males, was given olive oil alone by the same route, and in the same quantity. These animals served as the controls and numbered twice as many as the treated groups. There were no completely untreated controls in this study.

The tumor types reported for the gavage study were the same as those reported for the inhalation study, although 2 additional types of brain tumors and no uterine carcinomas were reported in the gavage study.

Dr. Maltoni noted that the incidence of tumors in the control animals in this study was "surprisingly high". In an attempt to determine whether or not this incidence of spontaneous tumors was within the expected range for this tumor type, Dr. Maltoni subsequently examined the histological data of 403 comparable control rats of uncorrelated experiments. He found 13 CNS tumors of spontaneous incidence in this group, a rate of 3 percent. While the 3 percent rate of spontaneous CNS tumors seen in Maltoni's historical controls coincides with the incidence of all types of encephalic tumors in his contemporary control animals in the gavage study, only 0.9 percent of his historical controls were gliomas, the type of CNS tumor generally considered to be treatment-related (Tr. 592). This compares to an incidence of 2 percent gliomas in the contemporary control animals in this study. (It is interesting to note that, though not statistically analyzed, the latency period of 33 weeks before tumor incidence in the single treated animal which developed a glioma is approximately one-third the 93-week latency observed in the three control animals which developed gliomatous tumors, indicating the possibility that the dose here was responsible for a decrease in the latency period.) Industry has claimed that this "partially undercuts" the MCA studies (Ex. 155). Dr. Maltoni nevertheless concludes, based on all the results observed under the experimental conditions used in these studies, that AN has shown a "borderline oncogenic [tumor-inducing] effect". He further states that:

> At present our data do not make definitive evaluations possible. On the other hand, they point to the need of further investigations on the long-term effects of AN (Exs. 13; 65).

Dr. Cueto noted in his testimony that this "borderline oncogenic effect" which Dr. Maltoni reports, was detected using only a minimally sensitive test. Cueto said that the number of dose levels Maltoni tested in the gavage study (only one dose level was used), the use of some very low doses (5 ppm and 10 ppm in the inhalation study), the low frequency of dosing (4 hours/day for 5 days/week in the inhalation study and only 3 single daily doses/week in the gavage study) and the short duration of AN administration relative to the total duration of the experiment in these experiments greatly reduced their sensitivity (Tr. 263, 265). Dr. Cueto added that:

> * * * Dr. Maltoni's data can be used in terms of supporting the fact that one is beginning to see a chemically related effect. He has found effects at certain sites which others have found in a drinking water study * * * [and] in another inhalation study. It's all beginning to come together (Tr. 264).

Dr. Cueto reiterated that these CNS tumors are rare, stating that:

> * * * I am relying on the fact that all of the studies that I have looked at that have indicated central nervous system [tumors] and one involves * * * over 7,000 animals, did not find but a matter of about one percent tumors, which means that the probability of picking from a very small sample and finding central nervous [system tumors] is very low * * * because it is a very uncommon tumor (Tr. 232-233).

In his paper, Dr. Maltoni states that "to our knowledge, there is no systematic research on the spontaneous incidence of central nervous system tumors in experimental rodents" (Ex. 13). In referring to this statement, Dr. Squire said that while "* * * that may be true in the European community, it certainly is not true in the United States" (Tr. 588). In addition to the reasons mentioned by Dr. Cueto, Dr. Squire thought that the results of Maltoni's experiments were not contrary to the MCA studies for several other reasons. He said that of the types of brain tumors observed in the controls in Maltoni's gavage study, the gliomas (the type generally considered to be treatment-related) showed a 2 percent incidence in the controls after 2 years. Comparing this to an incidence of gliomas ranging from 10 percent to 40 percent in the MCA study after just 1 year, he said further emphasizes the importance of the MCA's findings:

> * * * one cannot dismiss the decreased latency [shown] by one year vs. two years and an increased incidence averaging about 20 percent vs. an incidence of 2 percent (Tr. 592).

Dr. Plotnick noted during the hearing that Dr. Maltoni had concluded from his studies of AN that there was a suggestion of carcinogenicity. Plotnick said that this determination was made despite the poor design of these tests as a bioassay for a carcinogen. He, too, pointed to the short exposure times in both tests, the noncontinuous exposure regimen in the gavage study, and the total duration of the test of only 52 weeks followed by a period of nontreatment for an additional 52 (or more) weeks, noting that normally, carcinogen bioassays are run for 18 months or longer. (Tr. 682-683). While the experimental design of these studies significantly reduces their sensitivity and limits their usefulness in addressing the issue of AN's carcinogenicity, OSHA finds that the Maltoni studies, when viewed in the context of the Dow reports, provide additional supportive evidence of the ability of AN to induce cancer in animals.

Industry has further objected to the use of historical control data to support statements regarding the rare spontaneous incidence of the brain and stomach tumors reported. Vistron noted that "comparison to control groups in the MCA studies yielded statistical significance for only one tumor—the benign papilloma", arguing that "* * * [i]t is not scientifically legitimate to attribute significance to the other tumors by comparison to spontaneous tumor incidence [i.e. historical controls]" (Ex. 146). Dr. Cueto stated during testimony, however, that when observing the incidence of tumors, comparisons must be made with historical data to establish a baseline for determining what the expected results would be in the control animals. The purpose of such comparison he said, was to determine whether the controls were indeed responding as controls and to thereby check the accuracy of the results to be certain the experiment was conducted properly (Tr. 232; 234-235).

Vistron has argued that while Dr. Squire noted a spontaneous tumor incidence for central nervous system tumors of less than 1 percent, Dr. Maltoni had reported a 3 percent spontaneous incidence of CNS tumors in his controls (Ex. 146). Dr. Maltoni, however, noted in his paper that he thought the 3 percent incidence of spontaneous CNS tumors seen in the control animals in his gavage study was "surprisingly" high and used historical controls in a manner similar to that discussed by Dr. Cueto. Maltoni had, therefore, checked the historical spontaneous incidence of the tumors at his own laboratory and had found an historical spontaneous incidence of 3 percent for all CNS tumors and 0.9 percent for glioma (Ex. 13). (Interestingly, Dow also compared the incidence of brain tumors they had found in animals exposed to 20 ppm AN (inhalation) to historical control data (Ex. 14:(64)).)

It is apparent that in the evaluation of experimental test results, historical data is necessary to establish the context in which such results are viewed. This is accomplished either indirectly, by virtue of the investigator's own past experience, or directly, by literature search. The use of historical data relative to the studies in question in this proceeding is clearly valid.

Industry participants, noting the benign nature of the stomach tumors seen at increased incidences in the AN treatment groups in both the Dow and Maltoni studies, have questioned the extrapolation of these findings to human health risk. Vistron has stated that "malignant tumors in humans do not arise from benign tumors; instead they arise de novo" (Ex. 146). This, however, is a matter of speculation. While experimental animals can be serially sacrificed and routinely checked for the development of tumors which can thus be traced from the benign to the malignant, human cancers are frequently first diagnosed when they are, in fact, already malignant. It is impossible to know, in many cases, whether that malignancy had an otherwise innocuous and benign beginning or arose "de novo". This is illustrated by Dr. Woodward's statement at the hearing that:

> In man at least, it is apparent and unfortunate that a cerebral hemisphere gliomatus tumor, and this is the common site for gliomatos tumors, may obtain considerable size before any symptomatology or [clinical] findings occur (Tr. 1089).

Dr. Yodaiken testified that polyps of the gall bladder, stomach, colon, and larynx are all precancerous lesions in man, and that in animals, papillomas are known to be followed by the development of malignant squamous cell cancer when the skin is painted with a carcinogen. He concluded that " * * * [p]apillomas under experimental and under human conditions do in fact tend to become malignant in certain circumstances" (Tr. 1085).

Dr. Squire observed that although the stomach tumors seen in the drinking water study were lesions of hyperkeratosis and benign papillomas, these are characteristic of the early response of the stomach to carcinogens, occurring with very low spontaneous incidence in this organ, and are clearly treatment-related (Tr. 542). As noted earlier, the three pathologists from NIOSH, who also examined the slides from the drinking water study, concluded, as Dr. Squire did, that the stomach papillomas must be considered premalignant lesions.

In questioning the validity of extrapolating animal data to humans, industry argues further that "the forestomach of the rodent has no anatomical counterpart in man" (Ex. 92). It is important to note that carcinogens are not necessarily organ-specific (chloroform for example, induces hepatic carcinoma in mice and kidney carcinoma in rats and benzidine, which causes hepatic carcinoma in rats, induces bladder carcinoma in man). In particular, AN has, in fact, been shown to attack a variety of primary sites in animals with a similar lack of site-specificity being implicated in man (Exs. 5:(1); 5:(5); 5:(13); 42). Furthermore, the malignancy here relates to the cellular composition of the affected organ rather than to the structural configuration of the organ. The stomach papilloma under discussion occurred in the non-glandular portion of the stomach (in the squamous epithelium) which is, in fact, the same as the epithelium of the esophagus in man (Tr. 1086). (In this regard, it is interesting to note that a 6-month oral toxicity study using dogs resulted in early lesions of esophageal tissue in those animals administered 300 or 200 ppm AN in their drinking water (Ex. 11:(12A)).

These points aside, the matter of benign tumors as precancerous lesions in man is not what is at issue here. The argument raised by industry participants must be separated into its two component parts. The first facet of the argument deals with the significance of benign tumors in experimental animals in determining the carcinogenicity of certain substances. While there is some debate as to the significance of benign tumors which may arise in humans, the stomach papillomas in question in the animal studies are "tumorigenic lesions * * * of significant concern, as they are the kind that generally tend to be precancerous" (Ex. 6:(175 at G/86)). The second facet of industry's argument relates to whether a finding of animal carcinogenicity can be reliably extrapolated to human risk. In his testimony, Dr. Squire stated that:

> I think we can say that all animal carcinogens, unless there is evidence to the contrary, must be considered as potential carcinogens in some humans * * * [q]ualitatively one can say that unless one has specific evidence to the contrary, that we have to assume it is potentially a carcinogen in another animal or species (Tr. 565).

Several chronic and subacute studies have been cited by Monsanto as evidence that a "no-effect" level of more than 2 mg/kg/day (approximately 20 ppm) exists for exposure to AN (Ex. 11:(27)). As discussed below, this statement is not supported by the evidence cited. Among the reports on which Monsanto bases its contention is a study conducted in the late 1950's by Svirbely and Floyd in which AN was administered to CFW rats in their drinking water over a two-year period. The authors reported no significant pronounced effects in the organs and bone marrow smears of these animals (Ex. 5:(25)). Monsanto has claimed that this report indicates a no-effect level of 50 ppm for exposure to AN (Ex. 11:(27)). Because, to our knowledge, the data for these studies has never been fully reported, an assessment of the results is unreliable at best, and in light of recent findings by Dow/MCA, no such conclusion can be validly drawn from this report.

Monsanto has further claimed that an early chronic toxicity study conducted in 1947 at the George Washington University by Tullar established a "no-effect" level of 33 ppm in rats (Ex. 11:(27)). Although this 2-year feeding study was not specifically designed to investigate the potential carcinogenicity of AN, four of the test rats developed tumor-like growths. No such growths were found in the control animals, nor were any similar growths found in the approximately 400 other rats from the same stock or even in the breeding stock from which these animals were taken. In this regard, the FDA has suggested that the Tullar study "adds significance to recent findings of AN's tumorogenicity" (Ex. 6:(174)).

In arguing for the existence of a "no-effect" level for AN, Monsanto also references the findings of two 1975 Dow studies (as distinct from the chronic studies conducted by Dow and described in detail earlier in this document) in which AN was administered in the drinking water of experimental animals for relatively short periods of time.

One is a 90-day drinking water study in which concentrations of 500, 210, 85, 35 or 0 ppm AN were incorporated in the drinking water of male and female rats (Ex. 11:(12B)).

In the second study 4 male and 4 female beagle dogs/dose were given drinking water containing 100, 200 and 300 ppm of AN daily for 6 months (Ex. 11:(12A)).

Neither of these 2 Dow studies was designed to assess the long-term chronic toxicity of AN. To claim a general no-effect level on the basis of short-term exposures such as these, particularly when dealing with a substance which has been shown to produce cancer in animals, and to claim further that these are specifically "chronic animal tests for carcinogenicity," is scientifically unsound (Ex. 11:(27)).

In their final discussion of the toxicology data presented, Monsanto concedes that:

> Some of the toxicology studies discussed earlier do not have a direct bearing on the question of whether or not AN produces a tumorigenic or carcinogenic response in animals. They are cited to illustrate that the toxicology of AN has been studied in considerable detail (Ex. 11:(27)).

It must be clarified here that while the acute, short-term toxic effects of AN may have been studied extensively, research into the chronic effects of this substance has been very limited. It is for this very reason, particularly when it is noted that long-term effects of exposure to AN appear to be affecting the very systems in which effects have been noted in these acute toxicity tests, that the long-term results become increasingly important. As more data is accumulated, the need to minimize human exposure to AN becomes more apparent. The establishment of a so-called "safe level" of human exposure to AN is not possible when serious effects are being reported at increasingly lower dosage levels.

The manufacturers also point to Maltoni's research on AN as suggesting a no-effect level of approximately 2 mg/kg/day (Exs. 11:(27); 148) OSHA has discussed Maltoni's work at length earlier in this document. For reasons already stated and in light of the short exposure times, the non-continuous exposure regimen (in the Gavage study) and the short duration of the tests, OSHA views these studies as wholly insufficient to determine a no-effect level for AN.

During his testimony, Dr. Cueto addressed the issue of no-effect levels, or thresholds. He said that thresholds cannot be said to be established by merely noting the lack of a response. He said:

> • • • there [are] many ways you don't get a response. One of the ways is to have too few animals • • • The sensitivity of a test depends primarily on the number of animals that you use (Tr. 249).

He also stated:

> I think there are thresholds for every end point • • • the difficulty is in establishing them • • • [and] whatever the endpoint we are talking about, the thresholds may be different. So consequently the problem is that [while] thresholds do exist, establishing them is difficult; if you establish them, they are probably not meaningful in the real world (Tr. 239-240).

Dr. Edward Sowinski, Industrial Toxicologist for the Chemical Division of Uniroyal, Inc., similarly stated, during testimony that

> At this time, there is no scientific evidence available from either the MCA studies or duPont's epidemiology studies which indicate a safe level of exposure to acrylonitrile. A safe level may exist but there is presently insufficient data to identify such a level (Tr. 978).

Even if such no-effect levels for exposure to carcinogens could be established for animals, the validity of extrapolating such levels to man or even from one carcinogen to another for the same species would be highly questionable, at best.

The Assistant Secretary has addressed the issue of safe levels in previous rulemakings and has determined that based on the best available scientific evidence, no safe level for exposure to a carcinogen can be established at present (cf. Carcinogens, 39 FR 3758; Vinyl Chloride, 39 FR 35892; Coke Oven Emissions, 41 FR 46742; Arsenic, 43 FR 19584).

Another argument raised in support of the concept of a safe level for exposure to AN is based on the results of experiments concerning the metabolism of AN (Exs. 11:(12I); 2:(11A)). While OSHA recognizes that biological systems may utilize alternative metabolic pathways differentially in response to a variety of conditions, the results of the metabolic studies on AN which have been submitted to the record cannot be interpreted as evidence of a threshold for the carcinogenic effects of AN. The potentially wide variation in the metabolic response over time, along with the long latency periods associated with the carcinogenic response and the lack of definitive knowledge regarding many of the mechanisms of action involved in this response, make any conclusions regarding the metabolism of AN as based on short-term exposures, of questionable value when applied to the results obtained from chronic exposures. More importantly, the mechanism by which AN induces cancer is unknown; AN itself could be the active agent responsible for the transformation of normal cells into cancerous ones, or intermediates along known (or as yet unknown) alternative pathways may be involved.

The complexity of carcinogenesis, including the long latency period involved and the multitude of conditions relating to individual sensitivities to carcinogens make it difficult at this point in time, to demonstrate that exposure to any specified quantity of AN is safe. Because these uncertainties remain unresolved, and in view of OSHA's obligation to protect workers, we must conclude that no safe level for exposure to AN can be said to exist at this time.

2. *Evidence in Humans.* In May 1977, E. I. du Pont de Nemours and Co., Inc. (du Pont) made available to OSHA the preliminary results of an epidemiologic study of du Pont workers at the company's textile fibers plant in Camden, S.C. (Ex. 5:(5)). The study indicated excess cancer incidence and cancer mortality as compared with company and national experience.

The study cohort consisted of 1343 male employees who were determined to have had potential for exposure to AN at some time during the years 1950 to 1967. The morbidity or mortality status through 1975 was reported for 854 employees who began working in the polymerization area of the plant between 1950 and 1967 and who were still actively employed by, or had retired from, the company. Four hundred eighty-nine employees, or 36 percent of the defined study cohort, were workers who had either been laid off or had quit employment with the company, and whose vital status was unknown (du Pont is currently attempting to trace these employees) (Exs. 5:(5); 102).

One of the most striking observations of this report was that among the 470 male employees who had begun working in the polymerization area of the plant between 1950 and 1955 and who were either still actively employed by, or had retired from the company, there was an observed incidence of 16 cancer cases among the active employees, as compared with an expected number of 5.8 (based on company rates) or 6.9 (based on national rates). The differences between observed and expected cases were statistically significant. The data presented show a higher frequency of lung and intestinal cancer. However, as du Pont noted, these tumor types alone are not entirely responsible for the significant excess of cancer seen in the cohort. In addition, all cases of cancer found were reported to have occurred among those employees who were first exposed to AN between 1950 and 1952.

Du Pont also reported that mortality data for this group (i.e. those first exposed between 1950 and 1952) showed 8 cancer deaths, as opposed to 4.0 (company rates) or 5.1 (national rates for white males in 1970) expected. These differences were also statistically significant.

The report did not include information as to the levels to which employees were exposed, and no directed cor-

relation between specific levels of exposure and the increased incidence of cancer in this cohort was reported. Because little or no data is available on employee exposures to AN during this early period, du Pont attempted to group the potential exposure severities at their Camden plant by job classification. This classification was described as having been based on the recollections of a committee of management personnel who had been present at the Camden plant during the 1950-52 period and who purportedly had intimate knowledge of the worksite and employees. As no past monitoring data was available on which to base them, these ratings were completely subjective, and du Pont noted that:

> * * * it is quite possible for careful employees to have "low" exposure though assigned to "high" jobs and careless employees to have "high" exposures though assigned to "low" jobs (Ex. 102).

In fact, it is interesting to note that the listing of exposure information as related to the severity code used (where "severity 3" is the classification with the least potential for exposure for AN), shows that a "sizable number of persons with only level 3 severity of exposure developed cancer" (Ex. 5:(5)).

Due to the lack of objective sampling data and the subjective nature of the alternative methods used for estimating these exposures, any dose-response relationship which might be defined for this cohort remains largely a matter of speculation and cannot be accurately derived from the available human data. In any case, even if such a relationship were to be demonstrated, this would not necessarily establish the level which actually induced the cancers observed.

In their analysis of the du Pont report, NIOSH has stated:

> It is interesting to note that, in addition to these two specific sites (lung and intestine) cancer of eight additional sites (prostate, lymphosarcoma, Hodgkins, (penis), thyroid, nasopharynx, bladder, and pancreas) occurred among the workers in this cohort. As pointed out by the investigator, this nonspecificity of tumor site is reflected in animal studies in which acrylonitrile was ingested or inhaled.
>
> Interpretation of these results is severely limited by two major factors:
>
> (1) The vital status of a large proportion (36 percent) of the cohort has not yet been determined, and
>
> (2) Complete work histories have not been obtained to provide information on exposure to substances other than acrylonitrile.

Despite these limitations which others have also noted in this proceeding, NIOSH concludes that:

> * * * the excess of lung cancer and cancer of the large intestine in both the morbidity and mortality analysis is clearly suggestive of a cancer problem among acrylonitrile workers (Ex. 5:(13)).

NIOSH and others have further suggested the possibility that exposure of the du Pont employees to other toxic, and perhaps carcinogenic materials may contribute to the observed cancer excess, however, du Pont has stated that: "* * * the issue of other exposures in addition to acrylonitrile was considered at the time the epidemiologic study was done" (Exs. 5:(13); 118).

The possibility that these workers were exposed to asbestos has been noted by several participants as an important factor to consider in view of the almost universal use of this substance in chemical plants (Exs. 92; 93; 106). NIOSH addresses this point in their posthearing comment, noting that:

> * * * asbestos is not mentioned on this (du Pont's) list of (other) exposures (common to the cohort); nor did Camden plant personnel address asbestos as a common exposure for this cohort when questioned about any other carcinogenic compounds during a NIOSH walk-through survey conducted March 2, 1978. Furthermore, the study reported no cases of asbestosis among the cohort members (Ex. 141).

It must also be noted here that exposure to asbestos would be expected to have been the same for all workers in the plant including those who were not exposed to AN. If asbestos were responsible for the lung cancers seen in this cohort, one would expect to find a comparable excess of cancers in workers who were not in the AN cohort, as well. Such an excess was not reported by du Pont.

Du Pont's preliminary report did not include smoking histories of the cohort, but a followup report contained information on the smoking histories of eight persons in the cohort who had died of lung cancer. Six of these were in the 20-year latency group and two were not (Ex. 102). One industry participant has claimed that "smoking is the most likely cause of the excess lung cancers at the du Pont plant" (Ex. 146). While this is certainly possible, it is purely conjectural, as there is presently no information on the smoking histories of those workers in similar exposure categories and jobs who did not contract lung cancer. Proper evaluation of the effect of smoking on the incidence of lung cancer in this study must include the smoking histories of all members of the cohort.

The other exposures reported by du Pont to have been common to the cohort include methyl acrylate and dimethylformamide (DMF). No data addressing the carcinogenic potential of methyl acrylate was submitted to the record and du Pont has noted that while DMF is a toxic chemical, their research, as well as a thorough review of the literature on this substance (including NIOSH data) indicates that DMF is neither a mutagen nor a carcinogen (Ex. 106, 108, 93). OSHA concludes, on the basis of information submitted by du Pont, that exposure to these chemicals does not provide sufficient evidence to alter the finding of the carcinogenic potential of AN as indicated by the excess cancers seen in this cohort.

OSHA recognizes that in this, as in all epidemiologic studies, exposures to other chemicals must be carefully assessed. The complexities of carcinogenesis are such that the possibility always exists that other substances may have in some way contributed to the development of cancer in the exposed individuals. The multitude of known factors, as well as the many remaining unknown aspects of the carcinogenic response, must all be considered in the interpretation of such studies. It is for this reason that animal bioassays and other laboratory research play an important role in the evaluation of human data, and that conclusions as to the carcinogenicity of a compound must be based on the record as a whole.

Another issue relevant to interpretation of the du Pont study was raised by Dr. Lamm, on behalf of both Vistron and Borg-Warner. Dr. Lamm has taken note of the deficit of cancer cases observed in that portion of the du Pont cohort exposed to AN "within the 20 years following initial exposure" (Exs. 97; 129). In addressing this point, NIOSH has stated that:

> * * * at least three possible factors could have contributed to this situation:
>
> (1) The "healthy worker effect" whereby the population under study is biased toward excluding workers who are sick or otherwise unable to work;
>
> (2) The recognition of the long latency period (20 to 40 years) required between initial exposure to a carcinogen and consequent clinically evident cancer in the worker;
>
> (3) The fact that the vital status of one-third (484) of the population is still not available. All of these factors probably contributed to seeing less cancer in those workers with fewer than 20 years of latency (Ex. 141).

In addition, Dr. Lamm makes note of the fact that the author of the du Pont study has suggested that:

> * * * reanalysis of the data to consider incidence potential only during time of du Pont employment may alleviate this anomaly (i.e. the observed deficit of cancer cases) (Ex. 129).

While this deficit in cancers observed in the group whose exposure began after 1953 is certainly of interest, the excess of cancers seen in workers who do exceed the 20-year latency must nevertheless be viewed as a serious indication of an increased risk of cancer for those exposed to acryloni-

trile. Du Pont's epidemiologist has stated that:

> Based on these preliminary findings, it can be concluded that persons exposed to AN at the textile fibers plant in Camden, S.C., are at greater risk of developing cancer, as compared with company, national, and regional experience (Ex. 5:(5)).

OSHA recognizes that due to its preliminary nature, and the inherent uncertainties generally associated with retrospective epidemiologic investigations, the du Pont study contains several unanswered questions. However, the Agency has carefully assessed this study and has concluded that the results presented support the finding of carcinogenicity for AN as observed in the animal studies described above.

Another epidemiologic study has been more recently submitted to the record by the United Rubber, Cork, Linoleum & Plastic Workers of America (URW). This study, done for the B. F. Goodrich Co. and the URW by Dr. Monson, of the Harvard School of Public Health, is a retrospective epidemiologic study of cancer morbidity and mortality among B. F. Goodrich workers, including some with acrylonitrile exposure (Exs. 67; 163). The results of this study showed that among white male union members who had at some time worked in an AN polymerization area and/or an area in which polymerized AN was used, there was a slight overall excess of malignant neoplasms, although fewer deaths from all causes were observed as compared to those expected. An excess of lung cancers (7 observed/4.4 expected deaths), genitourinary cancers (2 observed/1.6 expected deaths and 6 observed/3.1 expected incidences), and Hodgkin's disease (2 observed/0.3 expected deaths) are reported, although data supportive of these findings are not clearly presented. No excess of intestinal cancers was said to have been observed in this cohort.

In concluding his report, Dr. Monson states:

> Given the excess occurrence (of cancers) in these departments, and in spite of the difficulty in determing the reason for the excess, prudence is called for with respect to current conditions. To the extent that men currently working in these departments are exposed to AN and other chemicals, exposure should be reduced (Ex. 163).

While there are differences between the tumor sites seen in Monson's study as compared to the du Pont report, the incidence of a wide variety of primary tumor sites observed in both studies is itself suggestive of some commonality, particularly in view of the animal data in which a similar systemic carcinogenic response was observed. However, the Monson cohort was known to have been exposed to many substances other than AN which are themselves implicated in the development of excess cancers of various sites.

Because of the preponderance of other exposures among the members of this cohort, and because the excess cancers seen cannot be adequately correlated with AN exposure in this cohort, it is OSHA's conclusion that the Monson study, in its present form, adds little to the evaluation of AN as a carcinogen in humans.

3. *Mutagenicity.* Chemicals which cause mutations in bacteria have been shown to be generally capable of causing cancer in experimental animals, and chemicals which are carcinogenic to animals are also generally regarded as potential human carcinogens (Ex. 109; 5:(14)-5:(22)).

The detection of carcinogens through mutagenicity testing has been shown to be 85 to 90 percent accurate in the *Salmonella typhimurium* assay as described by Joyce McCann et al. (Exs. 5:(14); 5:(15)). These authors have shown that the *Salmonella*/microsome mutagenicity test has been sufficiently developed and validated to be used as a rapid screening method for the detection of mutagens as animal carcinogens and as a complement to long-term animal testing for the detection of potential human carcinogens (Ex. 5:(14)). Another assay procedure with *S. cerevisae* has been shown to be about 60 percent accurate in the detection of those carcinogens which increase the rate of mitotic recombination (Ex. 5:(16)). Although these test systems are not 100 percent accurate and neither a positive nor a negative response absolutely proves a chemical to be hazardous or nonhazardous to humans, the use of both assay procedures significantly enhances the probability of detecting potentially hazardous chemicals.

Several researchers, employing a variety of methods, have investigated the mutagenic potential of acrylonitrile. Because it is both highly toxic and highly volatile, special precautions have been shown to be necessary when designing experiments to assay for the mutagenicity of AN. When this has been done, test results have consistently shown AN to be mutagenic.

Highly reproducible and statistically significant positive results were reported by Venitt, Bushell, and Osborne when, by modifying their technique, they were able to test for the mutagenicity of AN at levels which minimized the toxic effects of this chemical. Importantly, the authors demonstrated that the toxic effect on the mutation rate was dose-dependent. Previous tests for mutagenicity at levels 20 to 40 times that used in these tests, while reproducible and statistically significant, were characterized only as "weak" and "reliably demonstrable only within a narrow range of doses." At lower doses the toxic effects were minimized (Ex. 5:(19)). By utilizing an exposure chamber to reduce the evaporation of AN and to facilitate the control of the exposure atmosphere, Milvy and Wolff reported that AN produced mutations in three separate tester strains of *Salmonella typhimurium* at low atmospheric concentrations with exposures as low as 57 ppm resulting in mutagenic effects (Ex. 5:(17)).

More confirmatory evidence of the mutgenicity of AN was provided by Venitt et al. in experiments utilizing a factor described by McCann et al. which increases microbial sensitivity to the mutagenic effects of chemicals and was thought by the authors to be likely to enhance the mutagenic effects of AN. As expected, AN was more mutagenic in this system (Ex. 5:(19); 5:(22)).

Industry participants have pointed to evidence of negative findings regarding the mutagenicity of AN (cf. Ex. 11:(27)). Two studies done on six different strains of *Salmonella* which used neither the fluctuation test nor the exposure chamber methods showed no activity at all (Exs. 5:(16); 5:(24)). A NIOSH memorandum dated December 9, 1977, from Dr. Taylor to the NIOSH mutagenicity task force members which was submitted to the OSHA hearing record by Vistron (Ex. 137), noted that acrylonitrile was one of several substances previously considered positive and subsequently found negative for mutagenic acitivity in the Ames test as carried out on four tester strains of *Salmonella typhimurium*. This is not surprising in view of the variability of test results seen in tests in which the toxicity and volatility of AN are not adequately controlled for.

The wide variation of test results reported in the area of mutagenicity would appear to be closely related to the differences in the laboratory methods used and to the high volatility and toxicity of AN. Available evidence indicates that the tests which gave negative results were done under experimental conditions which made no adjustments for these factors. Without repetition under appropriately controlled conditions, these experiments cannot be considered as evidence that AN is non-mutagenic.

The manufacturers have stated that there is no evidence supportive of a connection between human health and bacterial mutagenicity, and that "attempts to indict AN as a carcinogen on the basis of mutagenicity, test results are tenuous at best" (Exs. 11:(27); 11:(18); 11:(13); 146). However, the FDA, in their initial decision regarding acrylonitrile copolymers, said:

> The present data raises certain implications of adverse effects of acrylonitrile. The

microbial system screening for animal carcinogenicity has produced several clear, highly reproducible positive findings, with negative results occurring only when a technique meant to overcome the problems of toxicity or volatility of AN was not utilized. In this situation, with the same number of studies finding positive results as those finding negative results, it would be improper to discount the positive findings. This view results in a strong implication of acrylonitrile being a carcinogen in higher animal systems (Ex. 6:(173)).

This view was upheld in the FDA's final decision on this matter and OSHA concurs (Ex. 6:(174)). The statistically significant and reproducible positive results in microbial studies appropriately designed to minimize the effects of AN's volatility and toxicity cannot be discounted, and must be viewed as suggestive of a carcinogenic effect in animals. OSHA recognizes that such evidence, in and of itself, cannot be regarded as definitive proof of the carcinogenic nature of AN. However, OSHA must view these data in light of the high percentage of accuracy associated with predicting animal carcinogenicity by such tests, and as a part of the entire record, which to date has continued to support the finding that AN is an animal carcinogen.

4. *Teratogenicity.* The effects of acrylonitrile ingested by pregnant rats, on embryonal and fetal development have also been recently studied in an attempt to further define the extent to which AN can affect biological systems.

In an evaluation of the teratologic effects of AN, Murray, et al. reported fetal malformations as well as evidence of embrytoxicity (Ex. 5:(4)). Doses of 0, 10, 25 and 65 mg AN/kg/day were given to pregnant Sprague-Dawley rats by gavage on days 6–15 of gestation. The highest dose-level was significantly maternally toxic and produced increases in a variety of malformations among the fetuses in addition to evidence of embryotoxicity. The next lowest dose, 25 mg AN/kg/day, produced less maternal toxicity and a low incidence of the same signs of embryotoxicity and fetal malformations. Despite the short exposure period, this dose resulted in erosion, ulceration and a thickening of the nonglandular epithelium of the stomach in the dams (Exs. 5:(25); 28). No evidence of maternal toxicity or effects on the developing embryos or fetuses was apparent at the lowest dose of AN administered (10 mg AN/kg/day). The possibility that maternal toxicity was the sole cause of the malformations seen in this study is discounted by the authors.

In reproduction studies of a series of nitriles, including AN, Svirbely and Floyd gave groups of Holtzman strain Sprague-Dawley rats 10, 100 and 500 ppm of the individual nitriles in their drinking water (Ex. 5:(25)). Data from two first-generation litters showed decreases in the indices of fertility, gestation and viability in the group given the highest dose of AN. Growth retardation was also seen in the offspring of this high-dose group and, in addition, a progressive muscular weakness in hind limbs of the females at the 500 ppm dose developed unexpectedly 16–19 weeks after the weaning of the second litter. (While this study was to be continued through three generations, the data for the succeeding two generations were not made available.)

Monsanto has noted that it is conducting a 3-generation reproduction study involving rats receiving 100 and 500 ppm of AN in their drinking water "to determine whether the paralysis described earlier [in the Svirbely and Floyd study] was reproducible" (Ex. 11:(27)). Monsanto stated that "(f)emales held for 20 weeks after casting of their scond litters have not shown signs of hind leg paralysis" (Ex. 11:(27)). Valid comparison of these studies is not possible at this time, however, since neither the strain of rat nor the test protocol used by Monsanto was reported.

OSHA concludes that based on available data, AN is teratogenic in the rat. Available experimental evidence neither establishes a level of safety nor allows for the adequate determination of a safe level for human exposure. In his evaluation of this data, Dr. Yodaiken of NIOSH, has drawn attention to the "possibility that intrauterine insults to the developing embryo may only manifest clinically in the offspring long after birth" (Ex. 42). In light of the carcinogenic effects of AN, any "safe" levels which might be proposed for the teratogenic effects of AN would, in any case, be irrelevant, since it is OSHA's view that current scientific knowledge precludes the establishment of safe levels for all carcinogens, including AN.

In fact, the FDA has reached a similar conclusion in its deliberations involving acrylonitrile:

> It appears from an evaluation of the testimony and evidence presented in this proceeding that a finding of safety for AN at this time would be premature and unwarranted, particularly in view of the severe irreversible effects which have been potentially attributed to AN. This is so, despite the fact that such a determination might well have been possible were the adverse effects of AN limited to acute toxicity (Ex. 6:(173)).

Based on the above and on the record as a whole, OSHA concludes that acrylonitrile poses a carcinogenic risk to workers and that, in the absence of a demonstrated safe level, employee exposure should be reduced to the lowest level feasible.

V. Permissible Exposure Limit

The final standard establishes a permissible exposure limit (PEL) of 2 parts per million (ppm) averaged over an 8-hour period. This represents the lowest level which OSHA believes is generally feasible. In determining the appropriate PEL, OSHA relies on the record of the proceeding and on policy considerations which lead the Agency to conclude that in dealing with a carcinogen or other toxic substances for which no safe level of exposure has been demonstrated, the permissible exposure limit must be set at the lowest level feasible. Such a determination is, in our judgment, justified by the nature of the hazard being dealt with, and by the intent of the Act.

The Assistant Secretary has determined that acrylonitrile is a proven animal carcinogen and that it must be regulated as a human carcinogen. No data is available to demonstrate the existence of a "safe" level of exposure to acrylonitrile. In the absence of a demonstrated safe level, and because of the irreversibility and long latency period for cancer, OSHA must conclude that, for regulatory purposes, no safe level exists. An erroneous determination that a threshold does, in fact, exist would lead to an irreversible and fatal illness. This would be inconsistent with OSHA's statutory responsibility to set a level which will assure that no employee will suffer material impairment of health.

This statutory responsibility also mandates that the level that is set must be feasible. The record indicates that even the most totally enclosed processes have the potential for leaks and spills of AN, and that certain polymerization processes are not amenable to total enclosure. Industry has recognized, and the record clearly reflects, that 2 ppm is the lowest level which generally can be achieved primarily by use of engineering and work practice controls in most polymerization operations and other areas in which AN is used.

OSHA recognizes that the setting of a permissible exposure limit for AN involves a careful balancing of the relevant factors noted above. OSHA has determined that 2 ppm is the exposure limit which most adequately assures, to the extent feasible, that employees exposed to AN will be protected. It is incontrovertible that a PEL of 2 ppm can be achieved almost entirely through engineering and work practice controls in the large majority of AN operations, ranging from the manufacturing of the monomer through polymerization. As was recognized in the preamble to the proposal, however, there are certain operations which, by their very nature, will require the use of respirators. Such operations, which include the cleaning of prefloc

from the interior of reactors and certain other maintenance and cleanup activities, do not generally involve exposures for the full 8-hour workshift. It is apparent that activities of this nature would necessitate respirator usage in any event, due to the often unknown concentrations of AN that are involved.

The scientific and policy determinations underlying the regulation of AN as a carcinogen were discussed at length in the preamble to the ETS and were the subject of considerable comment in the course of this rulemaking as previously discussed. These determinations are consistent with other OSHA regulatory actions for carcinogens which have been taken after considerable scientific debate. For example, see the preambles to OSHA's carcinogen standard, applicable to 14 selected substances, 29 CFR 1910.1003-1910.1016 (39 FR 3758) aff'd, *Synthetic Organic Chemical Manufacturers Assn.* v. *Brennan*, 503 F. 2d 1155 (3d Cir., 1974) and 506 F. 2d 385 (3d Cir., 1974); the vinyl chloride standard, 29 CFR 1910.1017 (39 FR 35892), aff'd, *The Society of the Plastics Industry* v. *OSHA*, 509 F. 2d 1301 (2d Cir., 1975), cert. den., 421 U.S. 992 (1975); the coke ovens emissions proposal (40 FR 32268 (1975)) and final standard, 29 CFR 1910.1029 (41 FR 46742 (1976)), aff'd, *American Iron and Steel Institute* v. *OSHA*, No. 76-2358 (3d Cir., 3/28/78); the DBCP emergency temporary standard, 29 CFR 1910.1044 (42 FR 45536 (1977)), and final standard (43 FR 11514 (1978)), and the inorganic arsenic standard, 29 CFR 1910.1018 (43 FR 19584 (1978)). See also OSHA's proposed generic cancer policy, which was published in the FEDERAL REGISTER on October 4, 1977 (42 FR 54148).

The preamble to the proposal discussed three alternative PEL's which were being considered as the "lowest level feasible": 2 ppm, 1 ppm, and 0.2 ppm. The basis for the choice of 2 ppm in the ETS was the general agreement among industry personnel that 2 ppm could be met in virtually all facilities through a combination of engineering controls, work practices, and respirators. Whereas the ETS permitted any practicable combination of these control methods to be used during the 6-month period of the ETS, it was necessary to determine what level could be reached in most operations through engineering and work practices alone for purposes of the permanent standard. Several companies have indicated in written comments, and others have noted in their testimony, that they have either reached 2 ppm or expect to reach 2 ppm within several months in most of their operations through engineering controls (Ex. 11:(14); 11:(25); 92).

The exposure limits in this standard are based upon what can be achieved by the affected industries taken as a whole, using available technology or technology looming on today's horizon. The alternatives to this approach have been considered in the context of the AN rulemaking. As will be discussed, there is considerable variability among AN manufacturing and processing facilities as to their capabilities of reducing AN exposures. The differences between operations primarily involve the methods of processing AN and its various polymers, the types of materials being produced, and the physical properties of both the monomer and polymers during processing.

Difficulties which may arise for individual operations or processes in particular plants will be considered at the compliance level, which is specifically oriented to consider problems at individual locations.

The feasibility determination as to 2 ppm standard is based upon analysis of the affected industries taken as a whole. One alternative to this course might have been to establish the lowest feasible level for each AN facility on a case-by-case basis. This approach would be extremely difficult to implement. It would strain limited agency manpower resources and restrict the Agency's efforts to deal with important health areas other than AN.

Another regulatory approach, not far removed from a plant-by-plant approach, would involve setting different permissible exposure limits for each respective sector of the AN industry. The rationale for this alternative would involve a recognition that some sectors are capable of reaching lower exposure limits than are others. Although this alternative has some merit, OSHA has decided not to implement it for the AN standard for several reasons. First, as the ECI report makes clear, the AN industry encompasses a relatively small number of companies and plants. Establishment of different exposure limits within such a small industry would result in a standard which was almost on a plant-by-plant basis. Second, the administrative difficulties of compliance with such a fragmented standard would be great, particularly for those companies having facilities in more than one industry sector. Third, the Agency itself would have serious problems in administering and enforcing a standard of this type. The AN industry is already well-defined, and further splitting of the industry for the purposes of setting different exposure limits would not be in line with efficient and protective regulation of occupational exposure to AN.

A third approach, one which was at least hinted at by industry questioning at the hearing, would be to base the determination of feasibility on a worst case basis, that is, those situations where the PEL is most difficult to meet. This alternative is also unacceptable. It would allow most workers to be exposed to exposure levels much higher than could generally be achieved through engineering and work practices throughout the industry. These workers would thus be subjected to an increased risk of cancer due to their added exposure to AN.

A fourth alternative would be the converse of the third alternative, basing the lowest level feasible on what could be achieved by the most advanced facility with the least extensive exposure problems. This approach would undoubtedly require widespread full-time respirator usage by most employees, since the majority of plants could not achieve such a low limit for most employees. Because of problems inherent in respirator usage (see section on respiratory protection), this alternative is not acceptable over the long run, although in given circumstances respirators may be necessary to provide health protection.

OSHA has determined that in regulating occupational exposure to AN, as has been the case in other standards, the PEL should be set at the lowest level achievable through engineering controls and work practices in the majority of locations, using available technology or technology looming on today's horizon. This approach is intended to provide maximum protection without excessively heavy respirator use.

OSHA has determined that 2 ppm is the lowest level feasible for the AN industry as a whole. This determination is based upon available engineering controls and those controls which can be adopted from other uses or which can reasonably be expected to be developed.

Not surprisingly, the AN industry has itself looked to vinyl chloride (VC or VCM) control technology as a primary source for the control of AN in the workplace. The production processes for the two monomers, as well as for many of their respective polymer products, are strikingly similar. In addition, AN users and producers, in developing plans to lower employee exposures to AN during the past year, have shown the ability to select appropriate control measures to apply at critical emission points of their production facilities. Many of these controls were developed from the vinyl chloride "arsenal," but as the NIOSH-ECI report makes clear, there is nothing novel or unique about their application for AN (Ex. 141). The data submitted by the industry itself makes clear that the companies are both aware of most of the VC technology

and capable of making it work in their facilities (Ex. 92; 86).

It is highly significant that the AN industry has itself clearly recognized vinyl chloride technology as the logical point of reference for engineering controls. Schroy of Monsanto, testifying for the Society of the Plastics Industry (SPI), concluded that a 2 ppm standard was technically feasible based primarily on the control technologies from the vinyl chloride industry. (Tr. 798):

> I believe * * * that the technology which has been developed for VCM has to be converted because of the difference in physical properties to AN technology. That is in a judgment a minimal amount * * * The conversion of the VCM technology would be minimal to the AN, yes, at the two ppm (Tr. 805).

A reliance on "transferred" vinyl chloride technology for control of AN reflects a phenomenon which arises often in the context of the control of toxic substances by engineering means. In the case of acrylonitrile, until early 1977, there was never either an incentive or a perceived need to reduce exposures to the one to two ppm range. Indeed, the previous standard of 20 ppm had been achieved almost universally in all operations involving AN. Further control of AN was not a primary engineering concern. However, with the development of the evidence of AN's carcinogenicity, it became necessary to examine methods of control which could be used for a material which had been thought to be "satisfactorily controlled." The obvious place to look, as the companies themselves have done, was to the technology developed for control of another monomer, vinyl chloride.

As OSHA recognizes, there are clear differences between AN and VC which make it impossible to apply unmodified VC technology to all processes using AN. However, these differences do not, as some would argue, render the technology totally non-transferable. The record reflects countless areas of production and use of AN in which VC technology has been both explored and implemented. Still other areas display sufficient similarity of machinery, process, or source of monomer release to make the application of VC control worthwhile in the AN context. Even companies with little or no background in vinyl chloride control have been able to apply VC engineering advances to their operations involving AN (cf. Ex. 92).

It has also been contended that even if control technology is implemented, the employer will not be able to determine whether the operation will meet the PEL until after installation. This is the case, it should be noted, with practically all engineering controls, whether they be for containing a carcinogen or for controlling any other workplace contaminant. There can be, at best, a reasonable expectation that any type of control will accomplish a set reduction in exposure. With few exceptions, such a reasonable expectation has been established for the AN industry to reach a 2 ppm PEL for most operations, through readily available or readily adaptable technology (Exs. 11:(27); 88; 89; 92).

The need for adaptation and modification of VC technology has been discussed at length by several witnesses at the hearing, as well as by NIOSH and Enviro Control (ECI), in documents submitted to the record. However, it must be recognized that the very existence of this technology is a giant step forward in controlling AN.

On the basis of the data on the record, OSHA agrees with NIOSH's statement as to the current state of engineering technology for control of AN:

> The technology either exists or can reasonably be developed to meet the proposed 2 ppm standard in most processes most of the time through engineering controls.
>
> The technology does not exist to retrofit most existing AN processes to meet the proposed 0.2 ppm standard through engineering controls.
>
> No one, either in industry or Government, knows the precise extent to which compliance with the proposed 1 ppm standard is possible through the use of engineering controls. With the noted exceptions of polymer stripping, there is no information to suggest that acrylonitrile would be more difficult to control than vinyl chloride. However, control of vinyl chloride at 1 ppm is a difficult engineering challenge, and should not be taken lightly. The use of respiratory protection is still required on occasion in all vinyl chloride plants (Ex. 141).

The feasibility of a 2 ppm standard has been clearly acknowledged by the primary users and manufacturers of AN and AN-based materials, both in their written submissions and in their testimony at the hearing. Coverage of the final standard runs almost exclusively to these companies, which represent the largest chemical, plastics, and rubber manufacturers in this country.

In his statement at the hearing, Harding of SPI said:

> Industry will * * * request that the permitted exposure level be set at 2 ppm, with an action level of 1 ppm both on an 8-hour TWA, and a 15 minute ceiling limit of 10 ppm. This level is regarded by the industry as technologically and economically "feasible" (Ex. 72).

Chappelear of Monsanto, after a description of the ABS/SAN process and comparison with PVC, concluded that:

> Attainment of the 2 ppm PEL/10 ppm ceiling is feasible given sufficient time and significant expenditure of money. Technology to fully achieve lower levels is not defined for the total industry (Ex. 74).

Davis of Goodyear stated that, on the basis of an internal Goodyear study on nitrile elastomer manufacturing,

> It has been determined that compliance with a 2 ppm permissible exposure limit can be achieved through implementation of available technology. While it can be achieved, compliance will be costly. It is generally considered to be technologically and economically feasible for Goodyear's facilities using AN (Ex. 89).

Burgess of Dow Chemical noted that most of our plants are already in the two to one (ppm) range. That, of course is on a TWA basis. On an excursion basis we are still having some problems and are meeting some excursion situations by the use of respirators (Tr. 899-900).

du Pont has determined that:

> With the exception of maintenance work, emergencies, and a few identifiable operations where it is necessary to augment engineering controls by personal respiratory protection, it is feasible to control employee exposure to 2 ppm 8-hour TWA and 10 ppm 15 minute ceiling. This is done principally by the use of exhaust ventilation, improved process containment and changes in job procedures (Ex. 11:(14)).

Vistron noted that in mid-1977, they had begun an engineering plan to lower employee exposures to 2 ppm or lower (Ex. 92). When asked why they had looked at 2 ppm specifically, Brinkley of Vistron responded:

> We believe[d] that 2 parts per million was probably a workable number and it was feasible; and being realists, we also believe[d] that we would have to reduce the current exposures (Tr. 1124).

Engineering modifications specified in Vistron's 2 ppm engineering plan were expected to be completed by September 1978 (Ex. 92).

Ceiling Limit. The final standard provides for a ceiling limit of 10 ppm as averaged over any 15-minute period during the workshift. The ceiling supplements the TWA exposure limit by restricting the number and extent of short-term higher exposures to AN which are permitted within the TWA.

Under a time-weighted average limit alone, an employee could potentially be exposed to brief periods of extremely high exposures to AN without exceeding the TWA. The high acute toxicity of AN, combined with the unknown chronic effects of short term high exposures to AN, make the inclusion of a ceiling limit a prudent action.

OSHA recognizes that the controls necessary to reach the 2 ppm TWA will, of necessity, reduce the number and extent of excursions above the ceiling limit. This is particularly true where an employee's TWA does not involve 8 continuous hours of low level exposure, but rather, shorter periods of higher levels of exposure. There are many such exposure situations in the AN industry. OSHA believes that any additional compliance burden imposed

by the ceiling limit will be mitigated by the acknowledged need to limit excursions in meeting the TWA.

Monsanto has contended that there should be no ceiling limit in the final standard, because ceilings are primarily designed to protect against acute exposure and not chronic toxicity (Ex. 156). However, OSHA has determined that the nature of exposure patterns in the industry, the many points of potential release of AN in the workplace, and the potential for high short-term exposures make a limitation of excursions within the TWA necessary to protect employees.

VI. Exemptions

Because of the presence of residual acrylonitrile monomer in virtually all AN-based polymers, it has been necessary to consider the potential for exposure of employees who process acrylic fibers, ABS resins, and other materials into finished parts and products.

The low level of residual AN in acrylic fibers, once they are crimped and cut, as well as the degree to which the AN is bound up in the polymer, makes the handling of acrylic fibers an unlikely source of acrylonitrile exposure. In order to release the residual AN from the dried fibers, it is necessary to heat them to their glass-transition temperatures, which would discolor and spoil the product. In addition, even if such temperatures were to be reached, the low amounts of residual AN which are present in the fibers (less than 20 ppm, from data submitted to the record) would not be expected to result in significant AN exposures.

Where the intermediate product is a polymer latex or solution, as with polymer polyols, there is a possibility of AN exposure of employees involved in the processing of that product into a final product. For example, where the product is processed by heat or pressure, as is done in polyurethane foam fabrication, residual AN monomer in the polymer may be driven off. If the stripping of monomer from the polymer before it is packaged for further processing is incomplete, there may be sufficient monomer left in the polymer to result in substantial exposures of employees handling it in subsequent processing operations.

The wide use of ABS resins in plastics manufacture provides a major potential source of employee exposure to AN. ABS resins are extremely versatile polymers, and they may be processed into finished products by almost any of the generally recognized thermoplastic conversion processes, such as injection molding, extrusion, and other basic thermoforming techniques. ABS plastics can also be mechanically formed into products by blow-molding or cold stamping of sheet plastic for example.

Besides being used alone to make fabricated products, ABS resins can be combined with other resins, such as PVC in various ratios, to produce products with wide-ranging qualities and capabilities.

Thermoplastic processing of ABS resins involves heating or melting of the polymer, followed by injection into a mold, extrusion of ABS into sheet or pipe, thermoforming of extruded ABS sheet plastic into products, or comparable processes. The processing of finished ABS resins into fabricated products does not appear to constitute a significant source of AN exposure.

Due to the nature of the polymer chains and grafts in ABS plastics, when they are heated to temperatures well in excess of their melting points, the polymers tend to revert to their component monomers or "depolymerize." This phenomenon would likely occur only because of an accident or abnormal situation, such as the overheating of an extrusion head. The available data indicates, however, that the resulting potential for employee exposure to released AN is remote (Ex. 156).

In the proposal, OSHA recognized that the potential for exposure to AN in the workplace extended to a multitude of workplaces, including many small fabricators, extruders, and other downstream processors of materials containing or made from AN. It was felt that extending the AN standard that far would be burdensome to both industry and OSHA, and would not be reasonable in light of the degree of exposure involved. Therefore, the proposed standard contained three alternative conditions by which a processor, user, or handler of PAN could be exempted from the standard. The concept of exemption for downstream employers was widely supported by witnesses appearing at the hearing. The exemption provisions themselves were the subject of considerable discussion as to scope of coverage and the clarity of the language.

Although there was no number included in the proposal, OSHA proposed that one condition for exemption be based upon a given level of residual AN in a given polymer. It was hoped that industry would be able to supply data to correlate the amount of residual AN with the air concentrations of AN which would result when the polymer was processed. This hope was only partially fulfilled. Several companies did supply data on release of residual AN during processing, but there was no way to establish a definite correlation between residual AN content and release of that AN into the workplace. Recommendations for "permissible" amounts of residual AN ranged from 20 ppm to 1,500 ppm and above (Exs. 151; 152; 156; 160). It became clear that the wide range of polymers made from AN varied greatly as to their propensity to release their residual AN during processing. Therefore, OSHA determined that it would not be appropriate to include an exemption provision in the final standard based solely on residual AN content.

Although little information was available at the time of the proposal concerning levels of AN in processing operations, various companies have since supplied test data for the record during the course of this rulemaking. This data has enabled OSHA to make determinations on the extent and scope of the exemptions from the AN standard.

The available test data indicates that there is no way, at present, to determine the extent of release of AN from PAN solely on the basis of residual monomer content. A number of other factors are involved, such as the method of processing, and the temperatures, and pressures applied to the polymer during processing. Although, as expected, polymers with high concentrations of residual AN (over 1,000 ppm) generally result in higher air levels when processed, there is no consistent relationship that can be established.

OSHA believes, nonetheless, that the available data in the record do support an exemption from the standard for all handling, use, and processing of finished ABS, SAN, and nitrile barrier resins. Testing conducted by Monsanto on resins containing as much as 1,000 to 2,000 ppm residual AN indicates that the processing of these materials results in 8-hour TWA exposures well below 1 ppm (Ex. 156). Similar testing by Dow has resulted in consistent findings (Ex. 160). Data submitted by Vistron at the hearing also showed extremely low air concentrations during processing of nitrile barrier resins (Ex. 92).

The downstream monitoring data available in the record also justifies exemption from the standard for ABS, SAN, and nitrile barrier resins. The results of air sampling performed in the workplaces of extruders and other processors of ABS/SAN plastic materials clearly show air concentrations of AN to be well below 1 ppm (Exs. 156; 135; Tr. 855).

Dow Chemical reports that they have continued their monitoring of ABS/SAN fabricators and have not yet found 8-hour TWA exposures above 0.2 ppm (Ex. 160). They also note a study by the State of Michigan which reports no detectable AN in an ABS fabrication facility (0.1 limit of detection) (cf. Tr. 892-894; Ex. 160).

The Society of the Plastics Industry (SPI) reports that they have gathered data showing exposures ranging from "none detectable" to just less than 0.2 ppm in polymer processing operations (Ex. 148). Although SPI did not supply the actual data, their findings are consistent with the other data available in the record.

OSHA has determined that the exposures in ABS/SAN fabricating and processing operations are sufficiently low to justify their total exemption from the standard. The AN exposures in these operations, as reflected in the data supplied to the record, are well below 1 ppm even for resins with residual AN levels as high as 1,500–2,000 ppm. Therefore, we find that there is no need to limit the general fabrication exemption for these materials by tying it to a specific residual AN limit.

Nitrile rubber is, essentially, the same material as the rubber phase encountered in ABS resin manufacturing. The materials produced in nitrile rubber manufacturing will usually be in one of three forms: latex (liquid), bale, or slab (both solid). The difficulty involved in handling latexes is discussed at length elsewhere in this section. Insofar as bale and slab rubber are concerned, however, there is nothing to indicate that the handling of these dried materials in the form of finished polymers should present any greater potential for AN exposure than finished resins or plastics. Therefore, solid nitrile rubber is included in the list of exempted materials in paragraph (a)(2)(i) of the standard.

There is considerable data in the record to indicate that acrylic fibers, after they are dried, no longer pose a significant risk of AN exposure. The comments and testimony of fiber manufactures show that residual AN levels in acrylic and modacrylic fibers are extremely low, and that the potential for release of the residual AN is remote (Exs. 11:(14); 149; 11:(27)). This was recognized by OSHA in the preamble to the ETS (43 FR at 2588), and it was assumed at the time that the exemption provisions of paragraph (a)(2)(i) would cover fibers. However, the objective data requirement in the proposal has caused great concern for users of the fibers.

In particular, apparel manufacturers stated that it was unclear who had to maintain the records of objective data to support the exemption (Ex. 11:(24)). In their view, since they were using a "product made from PAN," albeit three steps removed from the manufacture of the fibers, the standard would require them to keep records. OSHA agrees that such a requirement would not be reasonable and has clarified the standard accordingly. A specific exemption is included in the standard for acrylic fibers as finished polymers (after the drying stage of the manufacturing process).

The most difficult area to deal with in the context of exemption from the standard is the processing, handling, and use of latexes and other liquid mixtures. It is clear in the record that "latex" is a very broad term which can refer to the polymer at several stages of manufacturing. The "latex" which carries the highest potential for AN exposures in the workplace is the so-called "polymer intermediate" latex. This latex is essentially an active part of the polymerization process, and is a major source of exposures in the manufacture of ABS and SAN resins and nitrile elastomers, regardless of manufacturing process used. It is undisputed that this polymer intermediate, which releases AN monomer throughout its movement through the process, must be regulated by the AN standard.

There are also latexes which are the final products of the polymerization process. These latexes, which are basically solid polymer dissolved or suspended in water or other solvent, may or may not present a serious AN exposure potential. Union Carbide submitted valuable data on its latex products, which are used in paints, adhesives, and textile coatings (Ex. 151).

At the hearing Dr. Burgess of Dow stated that, on the basis of tests of latex containing 20 ppm residual AN, latex in general should be exempted from the AN standard (Tr. 895). However, he was unable to discuss the release of AN by latexes containing higher concentrations of residual AN than those tested by Dow (Tr. 901). The Union Carbide material submitted as posthearing data shows a wide range of airborne concentrations of AN during the formulation and use of paints, industrial coatings, and adhesives made from acrylic latexes (Ex. 151). Union Carbide's conclusions as to exemptions of those latexes and products varied greatly with residual AN content as well as the use(s) of such products and latexes.

It is our view that the kind of data supplied by Dr. Burgess would represent the necessary "objective data" to support exemptions for the materials tested by Dow, on an individual performance basis. Similarly, the data supplied by Union Carbide on their latex products which all contain less than 10 ppm residual AN, exemplifies the type of data which could support an exemption.

It is notable, however, the Union Carbide tested latexes containing far higher residual AN levels than do the company's products. Ironically, then, whereas the data would support exemption of Union Carbide's latex products, they also show why "latex" as such cannot be granted a wholesale exemption, or an exemption based solely on residual content, from the standard.

The Union Carbide data graphically illustrate why there can be no general exemption for all AN-based latexes similar to the one included for ABS/SAN resins and for acrylic fibers. The data reveal both a greater potential for the release of residual AN by latexes and a greater likelihood of higher concentrations of AN in the workplace air as a result. As Union Carbide has pointed out, the effects of ventilation are crucial to the reduction of AN levels during the use of AN-based latex. In addition, products formulated from latexes take many forms, and contain varying concentrations of materials.

There are no data to indicate that the residual concentrations of AN in the Union Carbide latexes are typical of all acrylic latexes in either amount or propensity for release. Similarly, the formulator of paints and other materials utilizing the latex may produce widely divergent potential exposures by varying the latex content of his products. Other than the Union Carbide submission, there is little data available for OSHA to use to compare the many available latexes and latex products in these particulars.

We anticipate that most latex producers will be capable of providing data to support exemption of their products under paragraph (a)(2)(ii) of the standard. However, it is not possible for OSHA at this time, to establish a broad brush exemption for all latex, based solely upon the Union Carbide submission. As with all other products made from or containing AN, latexes and other liquid mixtures can be exempted from the requirements of the standard under the performance language in (a)(2)(i).

Indeed, Wheeler, in his cover letter to the new data, recognized this likelihood:

> Union Carbide Corp. believes that the scope and application of the Proposed Permanent Standard be limited through exemption of users and formulators from the Standard where objective data indicates there is minimal effect on employee safety. We also recognize the difficulties in making such an exemption apply to all forms and compositions of polyacrylonitrile. We, therefore, strongly recommend that the statement * * * ((a)(2)(i) of the Proposed Standard) be retained, the standard to provide for unknown applications and future technological changes. Such statement should be in addition to any specific exemption or exemptions OSHA wishes to grant (Ex. 151).

In order for OSHA to exempt latex as such from the final standard, it would be necessary to set residual AN limits for each category of latex usage. As the Union Carbide data makes clear, the many intermediate and end uses of latexes would render this an

impossible task from an administrative and enforcement standpoint. It is far more useful, in our view, to treat the latex problem through a performance requirement and not through setting detailed specifications for residual content.

The difficulties encountered in granting a general exemption for latexes also arise in the context of polymer polyols, and, presumedly, other liquid mixtures. In brief, although many polymer polyols would be expected to qualify for exemption under the performance requirements of (a)(2)(ii), it is not possible to exempt all such materials based upon the data available to us. Union Carbide has provided data on processing and use of polymer polyols which indicate that most of these materials will not release airborne concentrations of AN above 1 ppm under expected conditions of use, processing, and handling (Ex. 152). However, the data do not indicate a clear correlation between residual AN content and resulting air concentrations. Further, the data indicate that certain polyols will, in fact, release AN well above 1 ppm. As is the case with latexes, we are confident that most polymer polyols will be able to meet the provisions for exemption under the performance requirements in (a)(2)(ii).

The exemption provisions are intended to relieve all employers who use, process, or handle the materials listed in paragraph (a)(2)(i) from obligations under the standard. The exemption applies, further, to products fabricated from these materials.

With regard to our discussion of "latexes," it is noted that certain types of latex are no more than finely divided solid polymer suspended in water. "Such a latex on air drying releases no measurable acrylonitrile" (Ex. 11:(13)). It is clear that if the solid polymer would be exempt under paragraph (a)(2)(i), then a latex made from that solid polymer would be exempt, as well.

The second basis for exemption included in the proposal would have set an arbitrary limit of residual AN for exemption of AN-based materials from the standard. As has been discussed in great detail, the exemption provisions as revised render such an arbitrary limitation unnecessary. In addition, there has not been any clear correlation established between residual AN content and air concentrations during processing.

The third basis for exemption, as proposed, provided that if materials made from PAN other than latexes and other liquid mixtures, were not heated or melted, such materials would be exempted from the standard. Several parties to the proceeding have suggested changes to this section SPI, in particular, has recommended that the "heated or melted" language be clarified in terms of temperature, specifically 170° F. This temperature, as was discussed at the hearing, represents the boiling point of AN (Ex. 148, Tr. 754). We recognize that processing operations which involve heating and/or melting of polymer generally require temperatures well in excess of 170° F. Therefore, we believe that 170° F is a reasonable upper bound for exempting the handling of AN-based solid materials. This change has been incorporated into the final standard.

The data in the record, however, clearly indicates that certain latexes and liquid mixtures will release their residual AN when they are processed at room temperature, such as during the application of industrial coatings, paints, and adhesives (Ex. 151; 152). As noted earlier, the standard provides that latexes and other liquids made from or containing AN can still be exempted from the AN standard under the performance language in (a)(2)(ii), though they are not included within paragraph (a)(2)(i) or (a)(2)(iii).

The "heating or melting" provision of the proposal was primarily designed to permit exemption of the transportation, handling, and mechanical processing (stamping, etc.) of solid plastics, resins, rubbers, and other materials containing or made from AN. In addition to the materials to be exempted specifically by paragraph(a)(2)(i), there may be other materials developed in the future from AN for which the "heating or melting" provisions might be appropriate. Therefore, with the one change noted above, the third basis for exemption from the proposal is carried forward to the final standard as paragraph (a)(2)(iii). Solid materials are exempted from the standard, if they will not be heated above 170° F, because there is no data to indicate that residual AN in these materials is either released in significant amounts or absorbed through the skin from solid resins, plastics, or rubbers.

The proposed performance exemption, which required that a material not "release AN resulting in air concentrations exceeding 1 ppm", has caused considerable confusion. What is meant by this capabiliy of release is an 8-hour TWA of 1 ppm, rather than an instantaneous release. Were this to be an "instantaneous release," it would be doubtful whether many polymers would be able to meet this requirement, particularly in the headspace of storage tanks and drums. In addition, OSHA's primary concern is the employee's potential exposure during the workshift. This concern is more directly reflected by an 8-hour TWA exposure potential. The standard has been amended to include the 8-hour time frame for AN release in the performance exemption, paragraph (a)(2)(ii).

It should be noted that materials which qualify for exemption from the standard are exempted from the entire standard, including the protective clothing, labeling, and training provisions. The only obligation of an employer operating under the exemption is to maintain the records of the objective data which serve as the basis for the exemption.

Under the ETS, many persons expressed concern about the showing that was required for the "performance exemption" provided in paragraph (a)(2)(i). In particular, they wanted to know how far away from the material did the measurements of "release" have to be taken, and what conditions represented the "expected conditions of handling, processing, and use which would cause the greatest possible release." Some of the manufacturers were uncertain as to whether they could provide adequate data along these lines due to the wide variability of downstream workplaces and processing conditions.

By including a performance-based exemption provision, OSHA has incorporated a broad, flexible means for an employer to be relieved of obligations under the standard. If a downstream employer can show that his processing operations are within the parameters which the manufacturer used in his testing, he can rely on that testing data for exemption from the standard. Conversely, if the testing conditions used are less stringent than those encountered by the employer, that employer cannot rely upon data from that testing to support his exemption.

In this regard, there is no need for specifying that measurements of air concentrations be taken at a certain distance form the test material. OSHA recognizes that employee exposure conditions can vary greatly between plants, even though they may be using the same materials. All that the standard requires is for the tester to specify the conditions of the testing, such as the temperature of heating, time of heating, distance of sampling probe from the surface of the material being tested, and the like. The duty is on the employer relying upon that data to show that his operating and exposure conditions are within the conditions of the testing.

Perhaps the most variable aspect of downstream operations is the amount of ventilation present in the individual plant. In most cases, the higher the rate of ventilation in the workplace, the lower the potential for AN exposure.

A manufacturer of a material made from AN cannot anticipate all possible

workplace conditions to be encountered in the further processing of his material. However, in developing data on the release of AN from his material, he can provide useful data by performing his testing on a worst-case basis, without any ventilation to dilute the AN emissions. By doing so, and by specifying the other parameters of his testing procedure, the manufacturer can demonstrate the propensity of his materials to release their AN. A downstream employer who receives data from this testing must then analyze his workplace conditions to determine if he can reasonably rely upon that data for exemption from the standard. If testing without ventilation demonstrated for example, that at 6 inches from the material surface, release of AN was nondetectable, that data would support exemption of virtually any conceivable downstream operation involving that material. Therefore, testing without ventilation would serve as a starting point, and might itself generate enough data to provide exemption for numerous processors.

It must be emphasized that the exemption provisions apply only in situations where an employee's AN exposure potential is limited to release from exempted materials. In order to claim exemption from the standard, the employer is required to demonstrate that all of the AN-based materials to which an employee is exposed are exempted under paragraph (a)(2). When an employee is exposed to both exempted materials and nonexempted materials, as would occur in many polymerization facilities, the employer would be obligated to take action to protect the employee from exposure to AN, as provided in the standard.

"PAN." A major issue in this rulemaking has involved whether "PAN," or polyacrylonitrile itself, should be considered a source of AN exposure under the AN standard. As noted in the exemption section in detail, the data submitted at the hearing and in posthearing comments indicate clearly that most PAN does not release its residual AN easily, and that where release does occur, the resulting air concentrations are well below the action level.

The major source of AN in the monomer and polymer manufacturing processes, other than liquid AN itself, is the material passing through the polymerization process. This partially polymerized material, referred to as polymer intermediate, contains considerable residual AN, which it continues to release throughout polymerization. As the data in the record makes clear, once this material completes the polymerization process and is dried, both its residual AN levels and its propensity to release airborne concentrations of AN are extremely low. This refers to resins and rubbers as well as acrylic fibers. Because, as a general matter, "PAN" per se is not the problem, there is no need to explicitly refer to PAN anywhere in the standard. Rather, the term "liquid AN" has been defined, for the purposes of the standard, to refer to both the liquid monomer and the polymer intermediate in the polymerization process.

It should be noted that some PAN materials may, nonetheless, be subject to the standard if they are not specifically exempted in (a)(2)(i) or if they do not meet the performance conditions spelled out in (a)(2) (ii) or (iii). OSHA has determined that the standard should provide for either inclusion or exemption of new and different products made from AN or containing AN which may be developed in the future.

In the final standard, OSHA attempts to remove many of the ambiguities and uncertainties which arose under the ETS. One of these areas involves the prohibition against skin and eye contact with "liquid AN and PAN." There is no data to indicate that skin contact with finished polymers, whether they be resins, latexes, or fibers, will result in skin absorption of AN. Even during the processing of those polymers which may release their residual AN above the action level as airborne concentrations, OSHA is not aware of any skin absorption problem. However, it is likewise clear that the handling of AN itself, as well as polymer intermediates produced during the polymerization process, does carry with it a significant skin exposure potential. OSHA believes that it is necessary to guard against any skin or eye contact with these liquid monomeric and intermediate polymeric materials, and has clarified the standard to reflect this point.

The terms "liquid AN and PAN" led to some confusion under the ETS in the context of skin exposure. There was considerable concern that the standard prohibited any skin contact with solid PAN, such as resins and rubbers, since the term "PAN" did not appear to be qualified by the term "liquid." The skin contact prohibition deals solely with the liquid phase. Therefore, the manual handling of resins and other solid PAN materials is not prohibited under the AN standard.

A further point of contention concerned the phrase "products made from PAN," in the exemption provisions. It was argued that the exemption should also cover PAN itself, as well as materials made from or containing AN which might not qualify as PAN, such as acrylamide. These materials would also be exempted from the standard if they met the specified conditions for exemption. OSHA agrees that it should be the performance of the materials in question that determines whether or not such materials are to be exempted from the standard. The final standard reflects this expansion of the scope of the exemption provisions.

VII. Feasibility

In setting standards for toxic substances, the Secretary is required to give due regard to the question of feasibility. Section 6(b)(5) of the Act mandates that the Secretary shall set the standard which most adequately assures employees' safety and health "to the extent feasible, on the basis of the best available evidence." Additionally, in the development of occupational safety and health standards "considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws."

Accordingly, OSHA analyzes both the economic and technological feasibility of proposed standards. OSHA makes such analyses available to the public for comment and testimony during the course of the rulemaking. Interested parties are given the opportunity to testify on the economic and technological impact of proposed standards at the informal rulemaking hearing, and to submit additional information on the issue of feasibility.

In developing a standard for exposure to acrylonitrile, OSHA has evaluated both the economic and technological feasibility of the proposal on the basis of the entire rulemaking record, including the information developed by ECI and submittals by the public. On the basis of the best available evidence, therefore, OSHA has determined, as explained in detail below, that the permanent standard is both economically and technologically feasible.

Only one substantial study was performed as to the economic and technological considerations of the proposed AN standard. This study, which was performed by Enviro Control, Inc. (ECI of Rockville, Md.), was contracted for by OSHA, and considered the feasibility of the three alternative sets of permissible exposure limits contained in the proposal (Ex. 15). Representatives of ECI participated at the hearing and were subjected to questioning by other parties to the proceeding. In addition, feasibility was expressly considered in other testimony at the hearing.

I. *Technological considerations.* Upon reviewing all the data, comments, and testimony in the record, OSHA concludes that the achievement of the permissible exposure limits established in the final acrylonitrile standard is technologically feasible. This determination reflects the nearly

universal agreement by the affected companies, as well as the conclusions of ECI, that existing technology and modifications of existing technology will be capable of reducing exposures in most operations to below the PEL.

The record indicates clearly that the operations which are the easiest to control, in most cases, are the AN manufacturing facilities. The manufacture of AN is essentially a closed process, as opposed to the more open manufacturing processes found in polymerization facilities. It is well recognized that the most effective way to limit exposures to toxic and carcinogenic materials in the workplace is to assure that the materials are enclosed in the system as much as possible. The primary sources of exposure in the AN manufacturing process are leaks and spills from pumps, seals, valves, and other breaches of the closed system. In addition, there is potential for exposure to AN in the tank farm and storage areas, as well as in maintenance operations whenever the closed system must be opened for cleaning or repairs.

Many of the controls developed for vinyl chloride can be applied and/or adapted for use with acrylonitrile. In particular, those controls which contain the monomer within the closed system, such as double mechanical seals, can be used with AN.

There is nothing about the physical qualities of AN which would make it more difficult to contain within a closed system than VC (Ex. 143). The physical properties of AN which differ substantially from VC (e.g., lower vapor pressure, presence as a liquid rather than a vapor at room temperature and greater solubility in water) are relevant insofar as cleaning up spills and detecting leaks are concerned, but should be of slight importance from the containment perspective.

Even when the question of leaks and spills does arise, however, the difference in physical properties does not necessarily make AN more difficult to clean up. Parties at the hearing contended that because VC escapes from a leak as a vapor, it is rapidly dispersed, and that when the leak is detected, a portable ventilation unit will control it without the need for respirators during repairs. They argued that AN, which leaks as a liquid, would drip or pour into the workplace, thus resulting in more persistent elevated concentrations of AN vapor. In addition, it was noted that AN spills would require both ventilation and respirators to be used during the cleaning process, and such use would be more prolonged because of the slower vaporization of the AN (Exs. 74, 76, 92).

However, not all of the consequences of the different properties of AN and VC are in the direction of making AN more difficult to control. Unlike leaks of VC monomer, which must be detected by a monitoring system, leaks of AN can often be detected by visual inspection of working surfaces, in a conscientious leak detection program. In addition, since AN is a water-soluble liquid, spills can be washed down with water into the process sewer or disposal system, thus limiting the time of exposure to vapors in the workplace (Tr. 1170). Respirator usage during cleanup would, therefore, be for shorter periods of time than has been indicated. The washing down of spills of AN has long been an established practice in the industry, owing to AN's solubility and biodegradability (Ex. 92).

The leakage of AN from the closed system in the manufacturing process is often unpredictable, since seals, valves, and other equipment are capable of failing without notice. In addition, some employees involved in maintenance operations and cleaning of portions of closed systems will inevitably have potential for exposure above both the TWA and ceiling limits. We recognize, therefore, that a limited amount of respirator usage would be necessary in AN manufacturing facilities regardless of the permissible exposure limits selected by OSHA. Respirators will also be necessary in certain operations in tank farms and loading facilities. OSHA is confident that, with the exception of fugitive emissions and inherently hazardous operations, the AN manufacturing sector can comply with a 2-ppm TWA and 10-ppm ceiling limit, through engineering and work practice controls.

The record of this proceeding indicates that of all elements of the affected industry, AN manufacturers are the furthest along in the development of controls for 2 ppm. Their facilities do not have to deal with the complexities of the polymerization process or unique properties of the materials contained therein. It is easier to maintain an enclosed system for monomer production than for polymer production. This point is readily acknowledged by the affected employers (cf. Ex. 11:(14); Tr. 1160). AN exposure in the manufacturing process (other than during maintenance operations) tends to result from fugitive emissions from valves, pumps, seals, and the like. In addition, since many facilities are located outdoors, there is considerable dilution of these fugitive emissions by winds and air currents.

In the manufacture of acrylic and modacrylic fibers, AN is released during the polymerization and during the washing, hot stretching, and drying of the fibers. The finished fibers, as has been noted do not represent a significant AN exposure potential. Most of the residual AN in the polymer is driven off during the manufacturing process.

The record indicates that fiber production is already operating generally in the 2-ppm range. There are occasional operations, such as maintenance and reactor cleaning, for which respirators are necessary in order to meet the permissible exposure limits (Ex. 11:(14); 11:(12)).

The most difficult compliance situation under the AN standard involves the manufacture of ABS and SAN resins, and nitrile elastomers. There are several reasons why control of AN in these operations is expected to be a more complex matter. First, the nature of the manufacturing process requires there to be a great deal of access to the product during polymerization. The product has a tendency to congeal on the inside of the reactor and other vessels in the polymerization process. The material must be removed manually at irregualr intervals in order to avoid clogging the process. Connected with the access requirement is the relatively high residual AN content of the material being polyermized, which is released throughout the polymerization process.

Stripping of residual AN from these materials is a far more complicated task than stripping vinyl chloride from PVC for several reasons. Since AN is much more soluble in water than is VC, it is more difficult to drive off from the liquid polymer intermediate. In order to drive off a comparable amount of AN, it would be necessary to use considerably more steam and/or vacuum than would be used for VC. In addition, the material to be stripped is, in the case of AN, much more sensitive as to its physical properties. The use of the amounts of steam and/or vacuum that would be needed to strip AN effectively from resin and elastomer intermediates would badly degrade the product and alter or destroy its physical properties. In addition, the polymer intermediates, when stripped, have a disquieting tendency to coagulate, or "flocculate," prematurely, even during the actual stripping, thus obstructing the manufacturing process.

Exposures to AN can occur throughout the ABS/SAN and nitrile elastomer manufacturing processes. Since the intermediate polymer latexes release their AN throughout the manufacturing process, from the monomer reaction vessels through the flocculation tank area, until after drying.

Exposures in the ABS/SAN and nitrile elastomer industry are the highest of the affected industry sectors, on a TWA basis. Exposures ranging up to 20 ppm have been reported by one nitrile rubber manufacturer, mostly in the flocculation tank area (Tr. 985;

999; Ex. 161). Whereas a number of other job positions might involve the employee being in the exposure areas for a small part of the day, the flocculation area requires frequent monitoring of the operation by the employee.

Many plastics and rubbers made from AN, are produced by "emulsion" or "suspension" polymerization. In these processes, the polymer is suspended in a water-based latex or other liquid solution. The suspended polymer has a tendency to agglomerate, forming viscous solidifying material called prefloc. Prefloc can clog up the manufacturing process, and must be removed periodically from reactors and other vessels (Tr. 762).

It should be noted that two major manufacturers of nitrile elastomers have testified that they could comply with a 2 ppm PEL in most of their operations, with one of them venturing that, with some exceptions, 1 ppm might be feasible (Tr. 978; 1020; Ex. 88; 89).

Some more advanced companies in the AN industry have expressed a degree of optimism as to the technological feasibility of levels lower than 2 ppm. Dow Chemical, which is already operating generally below 2 ppm noted that "We believe that levels of 0.2 ppm, and 1 ppm are technologically attainable, but would require significant costs and years of effort" (Ex. 11:(25); 2:(21)). Monsanto noted that they expect:

> With reasonable confidence to be able to achieve the 2/10 goals [2 ppm TWA, 10 ppm ceiling] * * * across all our manufacturing operations which include AN monomer, fiber intermediates and finished goods, and plastics intermediates and finished products facilities. The completion schedule for these engineering projects may extend over a period of more than 2 years (Ex. 11:(27)).

Even further, Monsanto predicts that this engineering program may result in exposure levels near 1 ppm TWA and 5 ppm ceiling in a number of process areas. In addition, they anticipate being able to define additional engineering solutions to meet a 1/5 standard (1 ppm TWA, 5 ppm ceiling), based on the results of their current engineering program, for most of their facilities. Implementation of 1/5 solutions, they noted, would take 2 or 3 years beyond the period for completion of their 2 ppm engineering program (Ex. 11:(27)).

Enviro Control, Inc. (ECI), the contractor for the economic and technological impact assessment of the proposed standard, concluded that "engineering controls will be technologically feasible for compliance under Scenario A (2 ppm TWA/10 ppm ceiling) in all segments except in periodic maintenance operations" (Ex. 15). In their report, ECI also determined that 1 ppm would be technologically feasible except for periodic maintenance operations and tank farm and loading areas, whereas 0.2 ppm could probably be achieved through totally enclosed processes with the use of chemical cleaners not yet developed, but in any event not for AN production or for tank farms, loading areas, or periodic maintenance operations. New plants were determined to be necessary for ABS/SAN and nitrile rubber manufacturing operations to meet the 0.2 ppm standard.

At the hearing, Dr. Bochinski of ECI expressed confidence that 2 ppm was technologically feasible (Tr. 324). However, on questioning, he admitted to great uncertainty as to the report's conclusions of industry's abilities to meet a standard below 2 ppm. In particular, the 0.2 ppm scenario was most doubtful becasue of difficulty of stripping monomer from polymer latex and the need for chemical cleaners to replace the manual cleaning of reactors (Tr. 324; 331-2). (The stripping problem also arises under the 1 ppm scenario, as discussed below.) There are, at present, no known chemical cleaners which can remove the prefloc and other materials from reactor walls without damaging the reactor lining or other components. (It should be noted that many AN-based plastics and rubbers are valued primarily because of their resistance to the types of chemicals and solvents that would be used as chemical cleaners.)

Even if such chemical cleaners were to be developed, ECI determined that new plant facilities would be required for resin and elastomer operations to meet a 0.2 standard. It is clear that a PEL of 0.2 ppm cannot be considered feasible, based upon either presently available technology or that technology which looms on the horizon.

The greatest amount of attention in this rulemaking was given to the question of which of the other two alternative proposed PEL's, 2 ppm or 1 ppm, was the "lowest level feasible." Whereas the capability to meet 0.2 ppm has been shown to be speculative, at best, the 1 ppm and 2 ppm PEL's are subject to more detailed scrutiny.

At the hearing, ECI expressed concern over the feasibility of the high rates of ventilation (30-40 changes per hour) that their report stated would be necessary to achieve a 1 ppm standard (Tr. 300; 312). In addition, there was serious concern about whether the industry could develop means of stripping residual monomer from polymers to reduce exposure during polymerization. In response to a question from McCleary of Uniroyal, as to the technical feasibility of 1 ppm as opposed to 2 ppm, for nitrile elastomers, Bochinski replied:

> * * * well, whenever you start stripping more, say at 2 ppm, my impression was they could get by without additional stripping. There was some additional stripping proposed at the one ppm level, in addition to get to the one level. And any additional stripping, the producer runs a risk of * * * In certain cases, certain products, my understanding was that with low molecular weight latexes and other kinds that you are not able to strip very much because then you destroy your product quality and it's unacceptable in the marketplace. Your options are closed. You have to do something else (Tr. 326).

Bochinski concluded that the stripping problem would be even greater for ABS resins than for nitrile rubber, because the intermediate latex tends to coagulate to a greater degree within the process vessel (Tr. 328).

The difficulty of stripping AN from polymers is well-documented. It results from a combination of factors: the nature of the polymer latex, the relatively low vapor pressure of AN as compared to VC, and AN's relatively high solubility in water (resulting in its tendency to remain in a water solution, emulsion, or suspension). Indeed, NIOSH has concluded that the stripping problem is the primary barrier to engineering control of AN to the 1 ppm level (Ex. 141).

In addition to stripping difficulties, the control of polymerization operations to 1 ppm is also limited by the degree to which these operations can be enclosed. Particularly in the case of resins and elastomers, the intermediate latexes and other polymer intermediates have a tendency to agglomerate. It is necessary for the system to be accessible in order for an employee to remove blockages of such materials from the process (Tr. 762). This results in higher potential exposures to employees in these areas, since the polymerizing materials are releasing residual quantities of AN as they pass through the process. As noted above, stripping of this residual AN at an early stage in the process is severly limited.

The effort necessary for compliance with the 2 ppm AN standard will not be insignificant. However, it should be recognized that the AN industry is in a much more advantageous position as to available control technology than was the VC industry at the time of the vinyl chloride standard. The vinyl chloride industry did not at that time have a comprehensive body of control technology from which to draw. The AN industry on the other hand, has the benefit of 3 years or intensive and largely successful technological development for controlling VC. It is clearly not necessary for such technology to be totally transferable to the AN context in order to be beneficial in developing controls for AN. In this case, however, as the record demonstrates, many of the engineering controls in use for VC can, in fact, be applied to

AN. Many companies in the AN industry, including some without any experience in dealing with vinyl chloride, have implemented or are presently implementing such controls as double mechanical seals, closed-loop sampling systems, and portable ventilation systems. It is noteworthy that an expert witness testifying on behalf of both Monsanto and the SPI, stated that vinyl chloride technology with minimal modifications would enable the industry to reach a 2 ppm standard (Ex. 76; 86).

In a paper presented at the American Industrial Hygiene Conference in May, 1978, Schoultz, Gideon, and Bochinski concluded:

> PVC and PAN processes and emission sources are of sufficient similarity to allow a significant level of transfer of control technology information. It is estimated that, except for certain operations (i.e., vessel cleaning), where sophisticated, long-term controls are required, excessive AN exposures in PAN plants can be reduced within acceptable levels as demonstrated in PVC Plants (Ex. 143).

It is recognized that the engineering controls implemented to meet a 2 ppm standard will often result in exposures at or below 1 ppm (Ex. 92; 11:(27)). The ability to reach 1 ppm does not, however, extend uniformly across the entire AN industry. In particular, it must be noted that the greates numbers of exposed employees are to be found in those sectors in which the prospects of reaching 1 ppm are the most remote, primarily in plastics and rubber manufacturing. This appears to be a function of the degree of process enclosure and automation that can be achieved in the various industry sectors. Whereas monomer manufacturing involves essentially a closed system, for example, nitrile rubber production requires a far greater amount of access to the material being processed.

Our determination as to the infeasibility of a 1 ppm standard rests not on the economics, but rather, on the technology of engineering controls for AN and AN-based materials. As will be discussed below, many of these compounds possess physical properties which render them even more difficult to control through implementation and modification of existing methods of stripping or process enclosure than was the case with vinyl chloride.

Chapter 4 of the ECI report dealt with the issue of technological feasibility of the three proposed sets of permissible exposure limits. ECI relied upon an examination of the effectiveness of proposed engineering controls in similar process applications involving vinyl chloride monomer, as well as discussions with AN industry officials, in their feasibility determinations.

The control methods listed in table 4-1 of the ECI report represent the contractor's findings as to the necessary technology for reaching each of the proposed PEL's. In OSHA's view, "technological feasibility" extends well beyond the limited definition employed by ECI in their assessment of the AN proposal. Nonetheless, on the basis of the Agency's own examination of the available technology and technology on the horizon, OSHA has determined that many of the control methods which would be necessary to achieve employee exposures below 2 ppm cannot be considered to be technologically feasible. In particular, these would include the need for considerable additional stripping of resins and elastomers, the development of chemical cleaners for reactors, and the use of extremely high rates of air flow in ventilation (30-40 air changes per hour), appear to fall into this category.

Many of the controls prescribed by ECI in their report, however, have been readily acknowledged to be appropriate methods of limiting AN exposure in the workplace. Such controls are, essentially designed either to enclose the processing operations more completely or to ventilate those areas in which further enclosure is not feasible. The use of ventilation becomes necessary when the materials being processed cannot be effectively enclosed, and wherever ready access to the processing machinery is required.

Double mechanical seals around pump or agitator drive shafts can be used effectively to isolate process liquids. These seals are pressurized with an inert liquid which will leak through before any process liquids can escape and expose the employee.

The effectiveness of a well-maintained double mechanical seal in preventing leaks of process liquids and vapors is supported by the data submitted by an industry expert witness (Ex. 76; 86). Another industry witness noted that a double mechanical seal "certainly would be a very adequate seal on a pump" (Tr. 1175). He also noted that his company is incorporating double mechanical seals "wherever they appear to be feasible and can be tested and evaluated" (Tr. 1162).

Two alternatives to double mechanical seals which were listed by ECI included "canned pumps" (totally enclosed pumps with no seals which can leak), and relocation of process equipment to provide for gravity flow. ECI's concerns as to the feasibility of these alternatives were echoed by industry (Ex. 92). "Canned pumps" can be damaged if process liquids contain solid particles, and relocation of equipment may not be possible given existing configurations and the need for the redesign and movement of pipes.

The control of AN in tank farms and loading facilities was found by ECI to be feasible for the 2 ppm scenario, but would be likely to require respiratory protection at lower levels. The technology recommended by ECI for these areas involved quick disconnects on pipes and hoses, movable local exhaust ventilation, vapor recovery systems, and the redesign of the work station to avoid extended use of awkward or heavy hoses or pipes by employees in the area.

ECI concluded that seals on pumps, valves, and gaskets would have to be properly maintained in order not to leak process liquids and vapors into the workplace. Such seals would require proper design and materials to avoid premature deterioration of the seal, whereas proper maintenance procedures and intervals would be necessary to assure protection. This conclusion was supported by the data on fugitive emissions submitted by Schroy (Ex. 76).

Sample collection from the process stream could be enclosed and provided with local exhaust ventilation, with the flow-through from the sample container being vented into the waste collection system. One company has reported the installation of closed circuit sampling valves as part of its plan to alleviate this problem (Ex. 92; Tr. 1127).

Many maintenance activities, such as reactor cleaning and "breaking" contaminated flanges, will probably require the use of respiratory protection, in any event. The use of remotely activated "blinds" can make "breaking" the flange unnecessary by allowing "blinds" to be inserted into the system without the employee having to contact the process contaminants.

Ventilation was determined to be necessary for those processes which are not readily enclosed, such as emulsion and suspension polymerization. ECI recommended air flow rates of as much as 30 to 40 air changes per hour, in order to reach the 1 ppm and 0.2 ppm levels. At the hearing, the ECI panel noted that such high ventilation rates might not be sufficiently feasible (Tr. 442).

ECI determined that two additional control methods (i.e. increased stripping and chemical cleaning of reactors) would be necessary for the industry to meet either a 1 ppm or an 0.2 ppm PEL. The record reflects that the technology to implement these control methods does not presently exist, and cannot be said to be "on the horizon."

The technology for stripping residual monomer from polymers is the main area of vinyl chloride technology which cannot be transferred to any appreciable degree to the control of acrylonitrile. As noted earlier, the limits of stripping residual monomer

from such materials as ABS resins and nitrile elastomers during the polymerization process represents the most significant difference in controlling acrylonitrile as opposed to vinyl chloride (Tr. 618; Ex. 141). The earlier in the process that residual monomer can be removed from a product, the lower is the potential at later points in the process for release of and exposure to that residual monomer.

Stripping of residual monomer from vinyl chloride (PVC) is relatively straightforward. PVC itself is highly resistant to the temperatures and other stresses inherent in the stripping process. The removal of residual vinyl chloride requires relatively little steam or vacuum, because of VCM's high vapor pressure. The physical properties of both AN and its polymer products make the stripping of residual monomer a much more difficult prospect.

Many of the polymer intermediates produced from AN are highly temperature- and pressure-sensitive (Tr. 762). When subjected to the stripping process, these materials will often coagulate in the stripper, forming in essence, their final products at a premature stage. In addition to clogging the polymerization process, this can result in unacceptable changes in the physical properties of the final products.

The vapor pressure of AN is, as noted earlier, considerably lower than that of VCM. This factor, combined with the relative affinity of AN for water makes it considerably more difficult to remove residual AN from water-based polymer solutions, suspensions, or emulsions. Even if the polymer were to remain stable throughout the stripping, the process would require far more steam or vacuum for removal of AN than would be used for VCM.

The relative sensitivity of ABS and SAN polymer intermediates to stripping is also a function of the presence of monomer and polymer in a solution or emulsion. In SAN polymerization, the polymer and monomer are in one phase, and that phase increases in viscosity as the polymer content increases. ABS polymerization has this same problem, but adds a rubber phase (AN-butadiene) which makes the mixture even more viscous. This can readily be distinguished from PVC manufacturing. PVC is insoluble in VCM, and precipitates out during the polymerization. This property makes the removal of residual VCM from PVC easier than removal of the more soluble AN from ABS/SAN suspensions or emulsions (Ex. 74).

ECI concluded that no additional stripping beyond that being performed at present would be required to meet a 2 ppm standard. However, insofar as additional stripping would be necessary to reach the proposed 1 ppm and 0.2 ppm exposure limits in many polymerization processes, particularly in the manufacturing of nitrile elastomers, these lower limits cannot be considered feasible.

The use of chemical cleaners to replace manual cleaning of reactors in the polymerization processes would also be necessary for compliance with the lower exposure limits. Chemical cleaning would make it unnecessary for employees to enter reactors. As noted by ECI, there are, at present, no known chemical cleaners which will work effectively in the ABS/SAN or nitrile elastomer manufacturing process (Tr. 331-2; 998a; 1121). The essential difficulty here is two-fold: first, the polymer materials which must be cleaned out of the reactors are prized for their resistance to the very types of chemicals which would be used to clean reactors and, second, there are no known chemical cleaners which will work on these caked-on materials without also damaging or destroying the linings or other elements of the reactors themselves (Tr. 368; 434). Reliance upon chemical cleaning would not, therefore, be considered to be feasible.

In summary, the ECI report supports OSHA's conclusion that a 2 ppm TWA with a 10 ppm 15 minute ceiling is technologically feasible for the affected industries, but that a lower standard cannot be considered feasible for the reasons noted.

Essential to an evaluation of the ECI report is an understanding of the relationship between its various sections. The cost estimates contained in section 5 of the report do not, in any way, reflect ECI's own engineering assessment of technological feasibility and the technology needed to meet each of the proposed limits. The cost figures for each industry sector were extrapolated by ECI using the cost data that they obtained from the affected companies. Except for the data contained in the supplement to the report, none of the cost estimates reflected any independent engineering judgment by ECI. Dr. Bochinski of ECI, in response to questioning, noted that: "I did not prepare the costs. I got the costs from industry" (Tr. 441).

The reason that this distinction becomes paramount is because of the efforts made by questioners at the hearing to merge the two sections of the report. It cannot be stressed too strongly that the cost estimates reported by ECI represent what the companies themselves felt they would need to meet the proposed levels. The cost estimates did not represent a detailed listing of the numbers and costs of the engineering controls and capital equipment that ECI felt would be necessary for compliance.

The costs submitted to ECI and included in the report, therefore, were indications of what the companies, and not ECI, felt would be needed to control exposures. As noted at various points in the record, various companies did not always agree with ECI as to what would be necessary (Tr. 485; 495-500). Dr. Bochinski clearly noted that the companies do not all have to employ the same control techniques (Tr. 479). Questioning by industry as to variability in control techniques, therefore, served only to elucidate this point.

In one instance at the hearing, a list of engineering changes and controls submitted by one producer was reviewed by ECI. Dr. Bochinski determined that in his judgment, there were certain items that should have been included that were not on the list (Tr. 495-499). This does not indicate, however, that the control methods as listed would not achieve the desired lowering of exposures.

Indeed, the company in question had stated that its planned engineering controls, which presumedly includes the list referred to above, were expected to reduce most operations to 2 ppm or less, when completed (by October 1978) (Ex. 922; Tr. 1135).

2. *Economic considerations.* In setting standards for toxic substances, the Secretary is required by section 6(b)(5) of the Act to give due regard to the question of feasibility. Section 6(b)(5) mandates that final standards be set which most adequately assure employee safety and health "to the extent feasible, on the basis of the best available evidence," and further requires that, in the development of occupational safety and health standards, "considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws." While the precise meaning of feasibility is not clear from the Act, it is OSHA's view that the term may include the economic ramifications of requirements imposed by standards. The determination that OSHA has the authority to consider economic feasibility factors in developing standards has been endorsed by the courts. *Industrial Union Dept. AFL-CIO* v. *Hodgson*, 499 F. 2d 467 (C.A.D.C., 1974); *AFL-CIO* v. *Brennan*, 530 F. 2d 109 (C.A. 3, 1975). As pointed out by the D.C. Circuit Court of Appeals, Congress did not intend the Secretary to promulgate standards which drive entire industries or large numbers of employers out of business. On the other hand, "standards may be economically feasible even though, from the standpoint of employers, they are financially burdensome and affect profit margins adversely." Further, the court

said, the concept of economic feasibility does not "necessarily guarantee the continued existence of individual employers" *Industrial Union Department, AFL-CIO* v. *Hodgson, supra,* at page 478.

In accordance with the Secretary's position, it has long been OSHA's practice to analyze the economic feasibility of proposed standards where significant economic impact on employers covered by the proposals seems likely, to make such analysis available to affected parties for comment and subsequent hearing prior to issuance of final rules, and to invite the submission of other information on the economic impact and feasibility of proposed standards. In developing a final standard, therefore, OSHA evaluates the economic feasibility of the final standard on the basis of the information developed by its own studies of the proposal and submissions by the public during rulemaking.

To assess the economic feasibility of the proposed standard for acrylonitrile, OSHA undertook a detailed study of the proposal's economic impact on various affected industries. This study was conducted for OSHA by Enviro Control, Inc. (ECI) (Ex. 15; 15A). The ECI study has provided basic economic data for the evaluation of the economic impact of the permanent AN standard on the major affected industries. Additional information for this purpose was obtained through OSHA's analysis of all other economic data, comments, arguments, and testimony submitted at the AN hearing, in prehearing comments, and in posthearing comments and briefs. On the basis of the best available evidence, therefore, OSHA has determined, as discussed in detail below, that the permanent AN standard is economically feasible for the affected industries.

The economic impact statement was prepared in accordance with Executive Order 11949 (42 FR 1017), as noted in the preamble to the proposed standard (43 FR 2612). A notice of its availability was published in the FEDERAL REGISTER on February 24, 1978 (43 FR 7669). Therefore, OSHA has not performed a separate regulatory analysis pursuant to Executive Order 12044 (43 FR 12661, March 24, 1978), which was issued over 2 months after the proposed standard was published (cf. Department of Labor Response to Executive Order No. 12044, Improving Government Regulations, 43 FR 22915, May 26, 1978).

The economic and technological assessment prepared by ECI (Ex. 15) was published on February 21, 1978, and a supplement was made available at the hearing, on March 22 (Ex. 15A). Opportunity was given to interested parties to comment on and to testify concerning the contents of the report. In addition, representatives of ECI were available at the hearing to respond to questioning concerning their findings as to the economic and technological feasibility of the proposed AN standard.

In the case of the proposed standard on acrylonitrile, three sets of permissible exposure limits were expressly included for consideration: 2 ppm TWA/10 ppm ceiling; 1 ppm TWA/5 ppm ceiling; and 0.2 ppm TWA/1 ppm ceiling. We have already discussed OSHA's determination that, on the basis of the record, the 1 ppm and 0.2 ppm alternatives are not considered to be technologically feasible. Therefore, detailed discussion of the economic impacts of the AN standard will concentrate on the 2 ppm standard which OSHA has determined to be technologically feasible for the affected industries.

It is abundantly clear on the record that the final AN standard will in no way threaten the viability of the acrylonitrile industry. The companies to be affected by the standard are not small, marginal companies, but, rather, include the largest chemical, plastics, and rubber manufacturers in the country. The estimated costs of compliance with the standard, even if accurate, are insignificant by comparison to the total sales and assets of the affected companies.

In addition, OSHA has assured, through the broad exemption provisions, that the standard applies almost exclusively to these primary users and manufacturers of acrylonitrile. Downstream processors and fabricators of products from AN-based materials will, for the most part, be exempted from the requirements of the standard.

A major contention of industry witnesses, particularly those representing polymer producers, involved the failure of the ECI report to analyze the economic impact of the proposed standard on "downstream" employers. For the most part, these employers are engaged in the fabrication of parts and finished products from AN-based polymers.

At the time of the report, there was little data available, either to OSHA or to ECI, upon which to base an assessment of the effects of the proposal on downstream employers. ECI chose to assume that the exemption provisions of the proposal would serve to exempt most downstream employers from the scope of the standard.

The impact of a 2 ppm standard, particularly when coupled with the more detailed exemption provisions in paragraph (a)(2), on downstream employers is minimal. The list of materials exempted from coverage by paragraph (a)(2)(i) represents most of the materials made from AN which will be processed, handled, or used by a downstream employer.

Based upon a thorough review of the record, OSHA has determined that a 2 ppm standard is both technologically and economically feasible for the affected industries. The standard provides sufficient lead time (2 years) for companies to complete the installation of engineering controls to achieve compliance with the permissible exposure limits. The record demonstrates that many employers in the AN industry, including representatives from each of the various sectors within the industry, are either already in compliance with 2 ppm for many of their operations, or are in the process of implementing controls to achieve that end.

The main area in which costs are expected to be significant is the installation of engineering controls. Other areas of concern, such as respiratory protection and protective clothing requirements, were addressed at the time the ETS was issued. It was, at that time, determined that there was sufficient quantities of protective equipment available for compliance with the ETS, and that the requirements were feasible for the affected employers. Because the scope of the ETS was broader than that of the final standard, OSHA anticipates that all employers to be covered by the standard were also operating under the ETS. Thus, the feasibility determination from the ETS applies for provisions appearing in both the ETS and final standard. The cost estimates prepared by ECI include the costs of respirators, protective clothing, and other materials to be required by the final standard.

Costs of Compliance. The greatest economic impact from the final standard is expected to fall upon the manufacturers of ABS and SAN resins and nitrile elastomers. However, even for this sector, the anticipated costs of compliance will be well within their capabilities. A lesser impact within the major sectors affected is expected for the manufacturers of AN monomer, acrylic fibers, and polyols.

The total estimated costs of compliance with the final AN standard, as determined by Enviro Control, Inc., are presented in table A below. These estimates reflect the data developed by ECI in their report, as supplemented by data received at the hearing and in post-hearing comments. ECI has expressly incorporated the cost data supplied by SPI in revising their final costs for the ABS/SAN sector. As will be noted in detail below, OSHA believes that the SPI cost figures substantially overstate the anticipated impacts of the standard on the ABS/SAN manufacturers. However, in the interest of providing an upper bound

estimate of the impacts of the AN standard, table A includes the SPI data. It is clear that the estimated costs of compliance with a 2 ppm standard will be well within the capabilities of the affected companies.

TABLE A.—*Revised ECI Costs of Compliance by Industry: 2 PPM Standard*

[in millions]

Sector	Capital	O & M	Total annualized
AN monomer	$14.4	$0.6	$2.99
Acrylic fibers	22.4	2.3	5.69
ABS/SAN resins	56.8	7.4	16.79
Nitrile rubber	14.4	1.1	3.45
Polyols	1.6	.3	.59
Total industry	109.6	11.7	29.51

An essential limitation of the extrapolation process used by ECI in developing industry-wide cost estimates is the inherent assumption that all plants within an industry sector are at the same stage of development in controlling AN exposures. The effects of this assumption on the overall cost estimates depend upon the degree to which the sample plant is representative of the industry sector as a whole. If the sample plant is more advanced than most, then the cost estimates based on the sample plant can be expected to understate the total compliance costs. On the other hand, if the sample plant lags behind most of the plants in the sector in controlling exposures, then the overall cost estimates can be expected to be overstated.

The ECI report does not lean consistently toward either of these alternatives. For example, ECI's cost estimates for the acrylic fiber manufacturers are based on data from a company which employs "solution polymerization" as its process. More of the U.S. fiber production capacity, however, involves "suspension polymerization," which is more difficult to control (Tr. 417-418). On the basis of that factor alone, the ECI estimates for the fiber production sector might be expected to be on the low side. However, on the other hand, the largest producer of acrylic fibers has reported that its controls for AN are further advanced than the sample plant appears to be (Ex. 11:(14)). This would indicate that the extrapolation of costs from the sample plant to the entire industry sector would result in the cost estimates being overstated.

The variability of this aspect of the report was recognized by ECI at the hearing. When asked whether he felt the cost estimates were understated, Dr. Bochinski replied, "Maybe in the 0.2 level we might have understated. In some cases, 1 ppm and 2 ppm in some segments; maybe not * * * It is a mix" (Tr. 384).

Another difficulty with the ECI extrapolation technique involves their use of a "typical plant" within each industry sector. The typical plant was determined on the basis of total annual production. The use of the "typical plant" was necessary to determine the costs of other elements of compliance besides engineering and work practice controls. These additional elements, such as respirators and monitoring equipment, were determined on a cost per plant basis using standardized costs for the equipment and estimated rate of usage.

ECI calculated the total costs of compliance for each major industry sector at each of the proposed alternative sets of permissible exposure limits. Cost estimates were supplied to ECI by various companies within the industry sectors affected by the standard. These estimates were then used to determine the compliance costs of a "typical plant" within each sector, based upon annual production in pounds. The typical plant costs were then extrapolated to the whole industry sector level on the basis of total annual production.

ECI's data base was limited to that data which the companies contacted were willing to provide to them. As noted at the hearing, except for the information in the supplement to the report ECI took the cost data as they received it, without independently reviewing it for proper engineering or accounting (Ex. 15A; Tr. 509). In addition, data was not received from within all of the major industry sectors. Considerable data was received for the nitrile elastomer sector, but no data on ABS manufacturing was supplied to ECI until the supplement was prepared. In determining the costs of compliance for the ABS sector, then, ECI used the nitrile elastomer cost figures (based on a 30 million pound plant) and extrapolated them to the ABS "typical plant" (figured at 200 million pounds) on the basis of similarity of process and process controls.

The ECI method of extrapolation relied exclusively on companies within each industry sector to supply what they estimated to be the costs of compliance for each of the three proposed exposure limits. ECI performed no independent engineering assessment of the data received from these companies. The data from the sampled companies represented what the engineering departments of those companies determined necessary for compliance.

There is no clear way to determine what specific cost items were included in each company's data. It must be assumed, however, that the engineers engaged in providing the data were not solely concerned with hardware. In developing engineering plans and estimates, the areas of downtime, lost production, and other consequences of the engineering changes are of great importance to the planner, particularly where these changes would necessitate nearly total shutdowns of plants or of individual production lines. An engineer would be expected, as a matter of course, to include projected costs of downtime and lost production in his estimates for a particular engineering job (cf., Tr. 1272-73).

OSHA recognizes, however, that there may be instances in which these "indirect" costs are either too speculative or otherwise incapable of being quantified. It is significant that the companies supplying cost data to the record during the rulemaking proceeding were most reticent about assigning numbers to these types of costs. One company stated that a 1-day shutdown of their facilities would cost $250,000 (Ex. 92). It was noted at the hearing, however, that the company already carries out periodic turnaround efforts, for which it does shut down facilities. During these planned shutdowns, an engineering expert for the company agreed that many different engineering changes could be made in addition to the programed maintenance activities during the shutdown period (Tr. 1129). The $250,000 figure, then, would not be due exclusively to the implementation of engineering controls, but would be attributable to a number of different functions within the facility.

The type of cost to be incurred directly determines the planner's ability to estimate its magnitude; some cost items are basic and must be assessed in connection with the engineering plan, whereas others may only be roughly projected, but are not at all reducible to dollar figures. The form in which the sampled companies in each sector supplied their data to ECI leaves the question open as to how much of either type of cost was included in their calculations. It must be assumed, lacking any information to the contrary, that the costs submitted by the companies reflected what their engineering departments determined to be necessary for compliance with the alternative proposed exposure limits. This necessarily would include those elements customarily assessed in engineering plans, while excluding those elements which could not be projected in dollar figures. Nonetheless, even if this assumption were erroneous, the question of downtime costs would not detract from the Agency's determination that the standard is economically feasible for the affected industry.

OSHA is satisfied that the data contained in the ECI report clearly demonstrates the feasibility of a 2 ppm

standard for all of the major industry sectors evaluated in the report.

AN Manufacturing. There is no question that a 2 ppm standard is economically feasible for the AN manufacturing sector. As has been stated throughout the record, AN manufacturing is essentially a closed process, with the greatest potential for exposures arising from fugitive emissions, leaks and spills, and during reactor cleaning and other maintenace operations. The companies have already developed engineering plans designed to tighten up their processes and limit points of process emissions into the workplace. The compliance costs for this sector of the AN industry should pose no serious economic impact on the four affected companies, which together produce 1.5 billion pounds of AN monomer per year.

The ECI cost estimates in the report for the AN manufactuing sector were obtained solely through a review of the OSHA rulemaking record. Until Vistron supplied additional data for the 2 ppm level (which ECI incorporated into the supplement to the report), the only data employed by ECI was from the du Pont and Monsanto submissions to the record.

The du Pont and Monsanto data as submitted were not broken down by product, but contained cost estimates for the respective companies' total AN-related operations. ECI took the data and attempted to split the costs up according to product. As will be noted, the efforts in this regard were not properly performed for the Monsanto data, resulting in cost estimates which were too high for the AN-manufacturing sector.

ECI assumed that the Monsanto data ($34 million incremental costs for reaching 2 ppm) covered the costs for their AN manufacturing and acrylic fiber manufacturing facilities only. However, as was noted at the hearing (Tr. 348), the costs supplied for Monsanto were for all of their operations, including their ABS manufacturing facilities. Therefore, ECI's figures for Monsanto's AN and fiber production are overstated. This is particularly evident in light of the fact that control of ABS manufacturing is expected to involve higher costs than controls for monomer or fiber production.

ECI averaged the du Pont costs with the Monsanto costs to obtain an average cost to apply to the AN manufacturing sector. Insofar as the Monsanto costs were improperly determined, the ECI estimates for this sector are clearly erroneous on the high side.

The difficulty with relying upon a "typical plant" in the context of monomer manufacturing is that there are only four companies which are in the industry, and no company has more than two plants. Any extrapolation from a "typical plant", therefore, will be limited by the total number of plants and the determination that any one plant is "typical" of such a small number.

After the initial ECI report was published, Vistron later supplied cost estimates for a 2 ppm standard for their monomer production facilities. ECI incorporated this data into their supplement and noted that the results were consistent with their previous figures for this industry sector (Ex. 15A; Tr. 511).

Acrylic fibers. ECI's estimates for the acrylic fiber industry were based exclusively on data received from Dow Badische. This data was scaled to the level of the "typical plant" and was extrapolated from there to the total acrylic fiber sector.

The difficulty with assessing the accuracy of the cost estimates for acrylic fiber manufacturing stems from two countervailing factors. The first concerns the type of manufacturing processes used in the sampled plant and in the overall industry, whereas the second has to do with the current exposure and compliance conditions in the various companies in the industy.

The Dow Badische facility which supplied data to ECI produces acrylic fibers by means of "solution polymerization." Solution polymerization involves the formation of polymer in a solvent, and the spinning of fibers directly from this solution. This method of production is not the most widely used means of manufacturing acrylic fibers. Most fiber production in the United States (over two-thirds, by one company estimate) involves "suspension polymerization" (Ex. 156). Suspension polymerization involves a formation of polymer in water. The polymer if filtered, washed, and dried, at which point the dried polymer is either stored for usage or taken immediately to be dissolved in a solvent and spun directly into fibers. In suspension polymerization, it is necessary to open up the process in order to isolate dried polymer. Because this system is much less totally enclosed than a solution polymerization process, it is more costly to reduce employee exposures at a suspension polymerization facility.

ECI acknowledged at the hearing that suspension polymerization facilities will cost more to control than solution polymerization facilities (Tr. 417-418). Since a solution polymerization plant was the source of the data used to estimate costs for the entire fiber sector, it is clear that this factor would result in an understatement of the total compliance costs. (It should be noted that other fiber companies had the opportunity to submit cost data to ECI, but did not do so.) It is not possible to determine with any degree of certainty how much the total costs would be understated. The data submitted by other fiber producers to the record would indicate that the difference would in no way constitute an economic burden to the affected industries.

A countervailing consideration in evaluating the cost estimates for this sector is the degree of compliance which already exists among fiber producers. At least two producers of acrylic fibers have reported that most of their operations are already operating at between 1 and 2 ppm on a day-to-day basis (Ex. 11:(14); 11:(10)). Since the total number of producers in the industry sector is not large, one would expect that ECI's estimates would be overstated insofar as they do not consider the advanced state of exposure control within this sector.

The 2 ppm standard is, without question, economically feasible for the acrylic fiber industry. Most producers are well along the way to compliance solely by means of engineering and work practice controls in most of their operations. The cost estimates supplied by ECI indicate that the compliance costs should not cause the affected employers undue difficulty. In addition, ECI's cost estimates undoubtedly include items and activities which most, if not all, of the producers have already implemented in their facilities.

ABS/SAN Resins—Nitrile Elastomers. The extrapolation procedure employed by ECI to determine compliance costs for the ABS/SAN sector and the nitrile elastomer sector of the AN industry has been strongly challenged by various parties to the proceeding. The points of contention primarily involve the following: The averaging of the costs for two nitrile rubber manufacturers which submitted data to ECI; the use of the nitrile elastomer costs to estimate the costs for the ABS/SAN sector; the formula used by ECI to extrapolate from nitrile elastomers to ABS/SAN resins; the size of the "typical plant" within the ABS/SAN sector; and the question of "return on investment".

ECI determined that the typical nitrile elastomer plant produces 30 million pounds per year. This figure has not been seriously questioned. The cost estimate for this "typical plant" were determined by averaging cost data received from two producers, Uniroyal and BF Goodrich. The cost data from these companies were widely divergent, leading some to conclude that an averaging of these figures would be of questionable validity in estimating total costs for the sector. The averaged cost data were scaled by ECI to the level of the 30 million pound "typical plant".

Data received after the ECI report was published have indicated that the

initial estimates in the report may not be very far off the mark for the nitrile elastomer manufacturers. Cost figures received from Reichhold Chemicals (Ex. 15A) and Goodyear (Ex. 89) are relatively consistent with the initial ECI estimates for this industry sector. The Reichhold data, when extrapolated to the level of the "typical plant" (30 million pounds per year), revealed cost estimates for capital investment to be $1.2 million for the 2 ppm standard. The Goodyear estimates of capital requirements for their production facilities, involving capacity of 31 million pounds (1976), were approximately $2.8 million for 2 ppm.

The findings as to estimated costs for the nitrile elastomer sector reflect the greater amount of data available to ECI on this sector in preparing their report. Nitrile elastomer production provided the largest number of plant estimates of all of the sectors sampled for the report (Tr. 508).

On the basis of their in-house assessment of the alternative proposed exposure limits, Goodyear concluded that 2 ppm was both economically and technologically feasible for their manufacturing facilities (and that even 1 ppm would be feasible) (Ex. 89). There is no reason to believe that the impacts of a 2 ppm standard on the other nitrile rubber manufacturers should be much more severe from an economic standpoint.

In summary, then, the available data on the nitrile elastomer industry indicate that a 2 ppm standard is both technologically and economically feasible for that sector.

ECI determined that the manufacturing process and the points of AN emission were sufficiently similar between nitrile elastomers and ABS/SAN resins to allow the control costs for nitrile manufacturing to be extrapolated to ABS/SAN manufacturing. This determination received considerable criticism from parties to the proceeding. Exposure conditions, it was contended, tend to be higher and more variable in nitrile elastomers. In addition, the "typical" nitrile plant is much smaller than ABS/SAN plant, and may involve different types of control problems.

In the supplement to their report (Exh. 15A), ECI included data which had been supplied by an ABS/SAN resin producer for the 2 ppm standard. The revised total cost for the entire sector (ABS/SAN) differed from the cost figures in the February 21 reported by only 2.5 percent.

The size of the "typical plant" in the ABS/SAN sector was determined by ECI to be 200 million pounds/year. The capital costs for the typical plant, based upon the nitrile extrapolation, were $6.8 million at 2 ppm. The capital costs based upon the later data from an ABS facility for 2 ppm were estimated to be $3.7 million.

ECI's extrapolation using the ABS plant data resulted in a much lower total capital cost for the ABS/SAN industry sector for the 2 ppm standard than did the extrapolation from nitrile elastomers. However, the estimates for operating costs (labor, materials, and utilities) from the ABS plant were considerably higher.

The main source of controversy concerning the cost figures for the ABS/SAN industry centered around the size of the "typical plant" selected by ECI. ECI determined that on the basis of their knowledge at the time, a 200 million pound per year plant was typical of the overall industry. However, in their posthearing comment, SPI indicated that the actual "typical" plant was closer to 62.5 million pounds per year (Ex. 148). Although SPI stated that this was the result of a survey of their member companies, there was no detailed explanation of why their description of a "typical" plant differed from that of ECI, nor was there a discussion of how they made their determination.

The method that ECI employed to scale the costs of the "typical plant" up to the entire industry sector involved the use of an engineering formula: Cost of equipment M=(Cost of equipment N)

$$\text{Cost for plant M} = (\text{Cost for plant N}) \left[\frac{\text{Capacity of plant M}}{\text{Capacity of plant N}}\right]^{0.65}$$

This formula allows for "economic scale"; for example, equipment costs for a 100 million pound plant will be less than twice the costs for a 50 million pound plant, even though production capacity is twice as much.

The plant (ABS/SAN) which supplied data to ECI produces 150 million pounds of resins per year. To estimate the cost for the "typical plant" with annual production capacity of 200 million pounds (according to ECI), the formula was employed as follows:

$$\text{Costs for 200 million lb. plant} = (\text{Cost for 150 million lb. plant}) \times \left[\frac{(200 \text{ million})}{(150 \text{ million})}\right]^{0.65}$$

$$= (\text{Cost for 150 million lb. plant})\ (1.21)$$

Thus, one can see that although the typical plant is ⅓ larger than the sampled plant, its capital costs are only 21 percent higher, using the formula.

Using SPI's determinations of the "typical plant" (only 62.5 million pounds/year instead of 200 million), the formula works the other way. Although the "typical plant" is only ⅝ as large as the "sampled plant" in this case, its capital costs will be more than half as much as the larger plant. Therefore, an extrapolation to the whole industry sector on the basis of the smaller typical plant will, in this case, result in a much higher overall capital cost. In addition, the other elements which are necessary in all plants, regardless of size, will increase in total costs because there are more plants to consider.

SPI's calculations of the costs for their 62.5 million pound "typical plant", using the ECI formula, result in a capital investment of $2.56 million. That figure, when extrapolated to the entire industry sector, results in a total capital cost for the ABS/SAN sector of roughly twice the figure arrived at by ECI.

ECI's estimate of the size of the "typical plant" was based upon their experience and engineering judgment. SPI's estimate was based on a survey of its membership of the industry. OSHA is unable to ascertan, with any degree of certainty, which approach is more accurate, nor is such a determination really necessary. OSHA has incorportated the higher estimate to establish an upper bound of costs of compliance for the ABS/SAN sector. We believe that this treatment of the available data provides an adequate basis for evaluating the economic impact of the standard.

Another major issue which arose concerning ECI's cost estimates, not only for ABS/SAN resins but for the entire report, was the treatment of the concept of "return on investment (ROI)." It was contended by several parties that the ECI cost estimates did not incorportate a return on investment as part of the overall costs of compliance with the standard (Ex. 76; Tr. 304; 393-4). It was argued that a failure to include an amount for ROI would result in an overestimate of the industry's ability to pass through costs to consumers as price increases. SPI, in the cost tables in their posthearing comment, chose to include an additional cost to represent the purportedly omitted figure for ROI, based on their assumption that such a cost was not incorporated in the ECI estimates (Ex. 148).

The record makes clear, however, that ECI did, indeed, include the concept of return on investment in developing their report. Dr. Henry Beale, a economist with Chase Econometrics, testified for ECI as to the handling of economic factors in the report. When questioned as to whether ROI was included in the capital cost estimates, Dr. Beale responded in the affirmative:

There is implicitly a 10-percent rate of return on investment involved in that the expenditures, the capital costs are based on an assumed useful life of 10 years recouped at the 10 percent rate * * * basically is (the same thing as ROI) (Tr. 302).

Therefore, SPI, in choosing to factor an additional 10 percent ROI into their calculations, has incorrectly assumed that no ROI was included in the ECI report. The additional 10 percent results in double-counting, and serves only to inflate both the total compliance costs and, consequently, the impacts of the standard on prices and competition for ABS materials.

SPI's estimates of the effects of the standard on competition are open to question on several counts. First, as noted above, the erroneous inclusion of an additional 10 percent ROI serves to inflate SPI's estimates of the standard's impact on ABS prices. By artificially inflating the total compliance costs, this element also increases the price increases which are necessary to cover those costs. Second, as noted earlier, there is no way for OSHA to verify whether SPI's "typical plant" estimate is more accurate than ECI's estimate.

To the extent that SPI's typical plant may be smaller than warranted, the compliance costs other than capital will be inflated, since many of these costs are based upon a cost per plant basis.

Finally, the SPI cost estimates, as do the ECI cost estimates, necessarily assume that the plant supplying the cost data is about average for the industry. There is every reason to believe that many companies, including some within the ABS/SAN sector, are well along the way in planning and achieving reductions of employee exposures to below 2 ppm. To the extent that companies have already installed or are already implementing requirements of the standard, the incremental costs of compliance will be that much lower. At least one producer of ABS/SAN resins already maintains most of its operations below 2 ppm (Tr. 899–900).

Even if the SPI cost estimates were to be accurate, the economic impact of the AN standard on the ABS/SAN sector should be well within the capabilities of the affected employers. The ABS/SAN market is one of the most buoyant of all products made from AN, and the demand for ABS and SAN resins is expected to grow considerably in the future.

Polyols. Polymer polyol production represented the smallest industry sector investigated by ECI in developing their report. Based upon data received by one producer, ECI estimated that the "typical" polyol plant has a production capacity of 53.3 million pounds per year. The ECI estimate of the total investment needed to achieve a 2 ppm standard was $1.6 million for the polyol production sector. The annualized compliance costs were estimated to be approximately $0.6 million per year.

Downstream employers. As discussed in the exemptions section, OSHA believes that the final standard will effectively limit coverage to those employers with the greatest potential for exposure to AN in the workplace. As was the case with the ETS, we anticipate that most downstream employers will be exempted from coverage. A determined effort has been made to clarify the exemption provisions and broaden their scope where warranted by the evidence.

Economic impacts. After estimating the costs of compliance with the proposed standard, ECI assessed the effects of these costs on economic indicators as related to the affected industries. The impacts on critical materials, market structure, productivity, employment, energy, and prices were examined for each of the major segments of the AN industry. The methodology employed in the analysis of these impacts was described at length in the report, and will be discussed here only insofar as major issues were raised during the rulemaking.

Critical materials. ECI determined that critical materials impact was not relevant for AN or AN-derived materials, since none of these materials are currently listed on the Department of Commerce's list of strategic and critical materials. They also determined that there would be no indirect effects on critical materials due to product substitution as a result of the standard.

Market structure. ECI concluded that it would be most unlikely that the costs of compliance with the proposed AN standard would have any significant impacts on market structure at the four-digit [sic] industry level for any of the industry sectors studied. Most of the sectors are already highly concentrated. The four firm concentration ratios range from 91 for ABS/SAN resins to 100 for acrylonitrile monomer production. The only major exceptions to this conclusion would be, in ECI's view, if one or more firms in the nitrile elastomer industry were to cease production, or if compliance costs for the ABS/SAN industry were to substantially eliminate possibilities for entry into this growing area by new firms. ECI determined that at the 2-ppm level, the costs would not be sufficiently large to cause either of these two eventualities to occur.

Productivity. ECI calculated the aggregate labor costs of the proposed 2-ppm standard to be $3,557,000 annually. Based on a work force of 5,130, the average loss of labor productivity for the entire AN industry was estimated to be 2.89 percent.

For the 2-ppm standard, output was estimated to decrease by less than 4 percent with several sectors, such as AN monomer and polyol production, having reductions in output below 2 percent.

Initial capital costs of compliance were estimated to be 27.2 percent of annual investment for AN production, as compared with 6 percent for polyols, and 48.3 percent for fibers. However, these costs were estimated to be as high as 139.1 percent of annual investment for ABS/SAN resins, and 554.4 percent for nitrile elastomers. ECI concluded that for AN, polyols, and fibers, the cost of compliance at 2 ppm would not have a significant impact on output. Even for ABS/SAN resins, ECI estimated that the growth prospects of the industry were sufficiently great to make the costs of compliance unlikely to produce any major reduction in output. The one area of concern to ECI at the 2-ppm level involved the nitrile elastomer sector. However, additional data submitted to the record by two major producers in this sector (Uniroyal and Goodyear) indicates that a 2-ppm standard is considered by them to be feasible, and is not expected to have the serious consequences projected by ECI (Exs. 88; 89).

Employment. At the 2-ppm standard, ECI anticipated that relatively small changes in output will occur, so that few, if any, workers will be laid off. Any workers that are displaced are expected to be reabsorbed through transfers to other jobs in their companies.

Energy. ECI projected that for the 2-ppm standard, energy consumption would increase for the industry by 62,535 barrels of oil per year, or 173 barrels per day.

As ECI noted, even if these amounts were quadrupled, they would be insignificant on a daily basis in comparison to the total energy consumption of the affected industry sectors (Tr. 444).

At the hearing, ECI was questioned concerning the energy costs contained in their report (Tr. 442–444). It was contended that these overall costs did not include the energy requirements for the high rates of ventilation which ECI felt would be needed for compliance (Ex. 76).

ECI did acknowledge that they did not include the additional energy costs from ventilation as a separate element of their total energy cost estimates. However, this is not to say that such additional costs were omitted from the report. As we noted in our earlier discussion of costs, ECI's cost estimates were based solely upon data supplied to them by companies within each

sector. ECI did not apply independent engineering judgment to the companies' estimates, nor did they break these estimates down by line items needed for compliance. Therefore, ECI's own determination of what was needed to reach 2 ppm was not reflected in the costs received from the various companies. If a company determined that ventilation was necessary, then it included ventilation costs in its estimates. Moreover, if a company factored ventilation costs into its estimates, it must, therefore, also have factored in the operating and maintenance (O. & M.) costs of such ventilation. These costs would be expected to include the energy costs of operating the equipment. Therefore, energy costs would be included in the O. & M. costs for each sector, based on ECI's extrapolations of the data as received.

Prices. Based upon their estimates of the compliance costs of the proposed 2-ppm standard, ECI calculated the cost per pound of product output for each industry sector in the study. Using that cost per pound, ECI then calculated a maximum passthrough of costs, using a markup factor of 0.94. Finally, the estimated price increase was supplemented by the amount of compliance costs from AN manufacture which would be passed through to the AN users. The following table represents ECI's calculations as described above:

Product	Compliance, cost per pound (cents)		Costs (percent of price)		Percent increase[3]	
AN monomer	0.20		0.74		0.70	
Acrylic fibers	.92		1.48		1.84	
AEN/SAN resins	[1]1.25	[2]1.25	[1]2.05	[2]2.98	[1]2.15	[3]3.08
Nitrile rubber	1.89		2.82		2.93	
Polyols	.18		.30		.36	

[1]0.94 markup and AN pass-on costs.
[2]ECI estimates from report.
[3]ECI estimates incorporating SPI cost data.

The table makes clear that based upon the cost estimates developed by ECI, the price impacts of the proposed AN standard of 2-ppm are all less than 3.1 percent, even when the SPI cost data is incorporated.

As was noted in the earlier discussion of costs, SPI recalculated the costs of compliance from the ECI data using a smaller "typical plant" (determined on the basis of a "survey" of its members), and adding a 10-percent "return on investment" (ROI) figured on an aftertax basis. Even assuming for the moment that the smaller "typical plant" was more accurate than that determined by ECI, we have serious difficulties in accepting the additional amount included for ROI, both in concept and in amount. As Dr. Beale made clear at the hearing, ROI was considered in the cost figures developed by ECI in their report. Therefore, the very inclusion by SPI of an additional element of ROI represents double-counting. In addition, the use of 10 percent after taxes is not a proper application in this context.

To the extent, then, that the SPI estimates include a double amount of return on investment, one can conclude that the resulting cost estimates, together with the projected impacts on prices of ABS/SAN products and materials, are considerably overstated.

Even if the overstated SPI cost figures for compliance capital were accepted, their own estimates demonstrate that the compliance cost to reach the 2-ppm level in a "typical plant" would only represent 11 percent of the total capital of a new typical ABS plant (Ex. 148). It is clear that to the extent that the SPI figures are overstated, the projected impacts of the standard will also be overstated, particularly as to SPI's dire projection for the ABS pipe industry.

Nonengineering costs. The major thrust of the economic impact assessment was directed at evaluating the impacts and costs of engineering controls to reach the permissible exposure limits. However, the other elements of the proposal, such as medical examinations, respiratory protection programs, and monitoring have also been examined. OSHA has determined, both from the ECI report and on the basis of the companies' submissions to the record, that virtually all of the affected employers have both the facilities and the resources necessary to implement these other provisions. Most of the affected companies have had medical surveillance programs for many years, and should have no difficulty in providing the medical examinations called for by the final standard. In addition, OSHA had determined at the time of the ETS that there were then sufficient respirators, sampling pumps, and other materials available for compliance. Since the scope of the final standard is, if anything, narrower than that of the ETS, it is clear that the findings of feasibility carry forward to the final standard.

As discussed in the exemption section, OSHA believes that the final standard will effectively limit coverage to those employers with the greatest potential for exposure to AN in the workplace. As was the case with the ETS, we anticipate that most downstream employers will be exempted form coverage. A determined effort has been made to clarify the exemption provisions and broaden their scope where warranted by the evidence.

ECI did not focus on downstream employers in their analysis of the costs and economic impacts of the proposal. They apparently assumed that the exemption would be as wide-ranging as OSHA intended it to be. In addition, ECI indicated that at the time they prepared their report, there was little or no data available on downtown exposures. The information supplied by the various companies during the course of the rulemaking has indicated that downstream operations do not, for the most part, represent a significant source of potential for AN exposure. Therefore, the omission of coverage by ECI of downstream impacts is not expected to affect the overall cost esitmates for the affected industries.

VIII. Benefits

The legislative history and language of the Occupational Safety and Health Act, as distinguished from some other environmental health and safety legislation, clearly indicate that Congress has already arrived at a judgment concerning the balancing of cost and benefit, with the result that worker safety and health are to be heavily favored over the economic burdens of compliance. Specifically, section 6(b)(5) of the Act provides:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws.

Thus, while feasibility is an appropriate consideration, the Secretary is directed to set standards which attain "the highest degree of health and safety protection for the employee * * *."

This does not mean, however, that a systematic evaluation of costs and benefits is not to be encouraged within the limits of the estimation techniques. In considering the issue of feasibility in this rulemaking, as in others, OSHA has carefully evaluated the cost of compliance which may be incurred by the affected employers and their ability to comply. Additionally, OSHA believes that a standard for a substance which has been found to pose a cancer risk to workers, in this case acrylonitrile, must assure maximum benefit (i.e., prevention of serious illness or death) constrained only by the limits of feasibility.

Acrylonitrile has been found to cause cancer in laboratory animals, and has been linked with excess incidence of cancer in employees. No adequate scientific basic exists, however, to determine a quantitative dose-response relationship at the lower levels of AN exposures necessary to reduce the risk as much as is feasible. The uncertainty in both the actual magnitude of expected cancers and in the theory of extrapolation from existing data to the exposure level set in this standard places the estimation of benefits on "the frontiers of scientific knowledge."

While the actual estimation of the number of cancers to be prevented is highly uncertain, the evidence indicates that the number is likely to be appreciable. A dose-response relationship, that is, a lower incidence of excess cancer at lower levels of exposure, is likely to exist at lower as well as higher levels of exposures to AN. Therefore, reduction in exposure to lower levels is accompanied by a reduced risk, even though a precise quantitative relationship cannot be established.

In general, widespread employee exposure to acrylonitrile did not begin until the 1950's. In view of the latency period usually associated with the induction of cancer, significant reductions in mortality and morbidity may not be seen in the AN industry for many years after this standard is effective. However, unless exposures are reduced now, OSHA believes that employees exposed to AN will be at increased risk of cancer for many years to come.

In light of the uncertainties connected with risk determination and extrapolation from animal studies and human epidemiology, OSHA believes that it is required by the statutory mandate to adopt a highly protective posture in considering the evidence for health benefits.

Parties to this proceeding have attempted to use the du Pont epidemiological data to indicate both the magnitude of the risk and the hypothetical "cost per worker protected" under the alternative sets of permissible exposure limits in the proposal (Ex. 92; 146). Where the health effectiveness of alternative approaches is extremely uncertain and likely to vary from situation to situation, OSHA believes it is appropriate to adopt the compliance strategy which provides the greatest certainty of worker protection within bounds of feasibility, even if the approach carries with it greater economic burdens for the affected employers.

The issue of whether traditional "risk assessments" should be performed has been discussed at great length in this proceeding. Perhaps the most accurate discussion of the uncertainties surrounding the regulation of acrylonitrile was presented by Dr. Henry Beale, testifying for ECI, in response to a question concerning OSHA's policy determinations:

> If you recall (Dr. Cueto's) testimony, most of it was centered around the issue of determining that acrylonitrile was a carcinogen; that is, simply establishing it.
>
> He alluded to the possibility also of developing risk factors, dose/response relationships and so forth. These, in terms of the materials that I have seen, have not been developed for acrylonitrile.
>
> Now, I would draw a distinction between, in a slightly technical sense, the term "risk" and the term "uncertainty." Risk is a situation of known probabilities. It is like if you were a bridge player and you were a good bridge player. You may be able to get a count on a suit that is out against you and know after playing nine rounds that it breaks four to one. And you have to finesse for the queen. You know the odds are four to one which person to finesse. Okay? That is risk.
>
> If you do not have information, you just don't know what the probabilities are, you are operating under uncertainty. And to use the bridge player analogy, getting a count on a suit is a fairly sophisticated operation. A bridge player who is just a beginner would guess, and he might even not finesse for the queen.
>
> That is uncertainty. *The situation which prevails in terms of acrylonitrile is a situation of uncertainty. We do not know what the risk situation is. That sort of precludes any additional attempts at quantifying further benefits* * * * (Tr. 421-422) (emphasis added).

OSHA's experience with assessments of the impacts of health regulations has demonstrated to us the futility of applying traditional cost-benefit analysis and methodology to the workplace health context. The basic assumptions of such approaches are always subject to serious questioning, and the change in one variable can result in major changes in the overall assessment. The analysis performed by Dr. James Miller for Vistron demonstrates clearly the limitations and weaknesses of both the assumptions and the results of such assessments.

Miller relied upon the du Pont epidemiological study as his source for data on cancer risk for employees exposed to AN. His first assumption was that the du Pont cohort was exposed to 20 ppm. This assumption, which is the touchstone of his later use of the "linear model," is severely flawed. It must first be noted that the du Pont Company itself has been unable to provide significant data on the exposure of its cohort. Miller's 20 ppm assumption was based not on information from du Pont, but, rather, on what another company (Monsanto) blindly estimated the cohort's exposures to be. Using the 20 ppm figure as a starting point for an evaluation of risk, therefore, is highly questionable.

The 20 ppm assumption is also unsupported by the data on AN exposures which is available in the record. Industry officials have frequently referred to the high acute toxicity of AN in describing the reasons for their early activity in instituting control measures in AN manufacturing and polymerization operations. Indeed, exposures have generally been well below the previous 20 ppm standard for many years. Twenty ppm is not far below the level at which acute toxic effects are noted. The companies have always recognized that AN is a dangerous chemical, even before evidence of its carcinogenicity became available. If a person could detect AN by odor (between 13 and 19 ppm), that was a sign to leave the exposure area. Because AN exposure is, in this range, self-limiting, it is most unlikely that employees were exposed to TWA's as high as 20 ppm. (Vistron's assertion that the industry standard in the early 1950's was 50 ppm is unsupported and, in any event, does not serve as evidence of the actual exposures at that time). Therefore, Miller's use of 20 ppm as an established exposure for the du Pont cohort is highly questionable on this ground, as well.

The impacts of the 20 ppm assumption on Miller's risk estimates become apparent when one reviews the "linear model" which was used in the assessment. As Miller acknowledged on questioning, if the actual exposures from the du Pont study were, in fact, 10 rather than 20 ppm, the line between the starting point and the origin would change in slope. He stated:

> (T)he reduction in risk per unit reduction in exposure would be twice that I have assumed. So it would mean that the cost figures per one reduction and by one chance in one thousand would be cut in half (Tr. 1278-79).

This acknowledgment by Miller is highly significant, particularly as it relates to the basic conclusions of his study. Even using his 20 ppm assump-

tion, Miller did conclude that a case could be made for a 2 ppm standard (Tr. 1270). If, as noted above, a more reasonable 10 ppm assumption was substituted, a case would be established for an even lower standard, purely on health grounds.

Taking Miller's study as it stands, we also believe that such an assessment ignores the element of externalities. The costs of illness and death due to occupational exposures to carcinogens are only partially absorbed at present by the industries involved. Employees and former employees must presently suffer most of the costs and losses resulting from occupationally induced cancer. The standard for AN will reduce mortality and morbidity among workers, thus relieving them of these costs. In essence, then, the affected companies are being called upon to internalize the types of costs which they had previously been able to externalize. To the extent that the costs of illness and death related to workplace exposures would have been incurred, the costs of protecting employees from occupational diseases do not represent new costs to be borne, but, rather, substitute costs. Further, the costs of engineering controls may, in many cases, be expected to cover more than one generation of employees in a given worksite.

The "linear model" is a useful tool only in those situations where one can demonstrate a true dose-response relationship for an exposed population. This requires, by definition, a showing of a known effect/no effect level. For AN, we have no data to indicate at what point this level is reached. In this regard, if the cancers in the du Pont study are traced directly to AN exposure, it is impossible to determine at what level of exposure these cancers were actually induced. We cannot rule out the possibility that employees with higher exposures did not, in fact, have their cancers induced by lower concentrations of AN.

In the case of the acrylonitrile standard, the evidence in the record overwhelmingly demonstrates that the costs of compliance with a 2 ppm standard will not be overly burdensome to industry. Having determined that the benefits of the standard are likely to be appreciable, OSHA is not obligated to carry out further exercises towards more precise calculations of benefits which would not significantly clarify the ultimate decision.

OSHA has, in the past, attempted to obtain a more detailed quantification of benefits to be attained under proposed standards. Previous efforts in this direction as an aid to decision-making have not been fruitful (41 FR 46742), and have provided little, if any, assistance in setting final health standards.

In summary, then, OSHA is promulgating this final standard in light of the specific mandate provided by section 6(b)(5) of the Act: to provide the greatest protection for employees, with consideration being given to the latest available scientific data, feasibility, and experience under the Act.

IX. Environmental Impact Assessment

In the preamble to the proposed standard (43 FR 2608), OSHA stated that it had made a tentative determination that the AN standard would have no significant environmental impact, and that preparation of an environmental impact statement (EIS) was not required. At that time, we solicited comments and data on this determination and information relevant to the issue of whether significant environmental impacts could be anticipated. Written comments were received from several participants in the rulemaking proceeding in response to the proposal (1-5).

The basic argument presented by all of the comments was that OSHA had erred in not preparing an EIS, because environmental impacts would occur as a result of the proposed regulation. The companies referred to general areas of impact, such as increased water usage, increased production of waste water, increased air emissions, and changes in solid waste disposal. However, no specific examples or data quantifying the extent of these potential impacts were provided to support the contention that significant impacts would occur.

In making the initial determination that the proposal would result in no significant environmental impacts, OSHA relied on the information available at the time, which indicated that the standard would have little, if any, impact on the current levels of air and water pollution, and minor impact on waste disposal practices.

Since the proposal was published, we have reevaluated our determination not to prepare an EIS. Although we still maintain that the impact on the environment as a result of this standard will be insignificant and that an EIS is not required, we are endeavoring to present a discussion of the areas which could potentially be affected to any noticeable degree. The control methods which will be used to limit employee exposure to acrylonitrile are more completely discussed in the section dealing with technological feasibility of the standard. The following is an assessment of the environmental impact potential of the standard for occupational exposure to AN.

1. The proposed action was designed to control occupational exposure to acrylonitrile. Only the workplace environment of 43 plants and the approximately 5,130 exposed employees involved in AN monomer production, processing, and use will be directly affected by the standard. The nature of this effect has been discussed in detail above. The general physical or natural environment external to the workplace will not be significantly affected by the proposed action, in that employers' efforts to comply with the standard will not significantly alter current levels of environmental emissions from the affected industries.

The following paragraphs outline the major AN industry segments which will be affected by the standard, in somewhat less detail than the discussions of technology and feasibility elsewhere in this preamble. Each segment will be reviewed as to the major sources of employee exposure to AN, ways in which such exposures may be controlled, and how control of exposures may impact the general environment.

AN Monomer Production. Employee exposures to AN in the monomer production segment of the industry occur as a result of product sampling activities, process leaks, accidental spills, storage and transport of AN monomer, and fugitive emissions. Methods which will be used by employers to reduce employee exposures include the following: more complete enclosure of systems to prevent release on AN into employee work areas, the use of exhaust or dilution ventilation in areas where leaks cannot be eliminated or where system enclosure is impractical, use of improved seals and gaskets to control employee exposures both during normal operations and product sampling, and immediate washdown of AN spills to prevent the generation of persistent high concentrations of AN vapor in the workplace.

Most, if not all, of these control methods are already in use to some extent in the AN monomer production facilities operating in the United State. The standard will result simply in more agressive control of employee exposures than has been the established practice to date. The control methods will not result in an increase in the amount of AN released to the ambient air, and, in fact, may reduce the current levels of emissions somewhat. Such a reduction would result from the improved control of leaks and other fugitive emission sources which presently expose employees and which inevitably reach the extenal environment. This reduction of exposures may be highly significant insofar as the health of employees is concerned, although the total amount of AN involved would be very small on an absolute scale. The total reduction in pounds of AN released to the environment would be expected, therefore, to

be insignificant in terms of overall environmental impact.

Washdowns of spills into process sewers to prevent employee exposure to AN is already a common practice. Thus, no significant increase in the amount of water used for this purpose is anticipated.

In addition, washing down of liquid AN serves to remove AN which would otherwise vaporize into the air. Thus, whereas there might be an increase in the amount of AN into process waste water, there would also be a corresponding decrease in emissions into the air.

Treatment or disposal of contaminated waste water is already being accomplished by one of two methods (biodegradation or deep-well injection) at all five AN monomer production facilities. The OSHA standard for control of employee exposure will not affect the waste water treatment methods currently practiced by the industry, nor will it result in higher levels of AN in the environment.

Acrylic Fiber Production. Exposure of employees in acrylic fiber production occurs when the monomer is being transferred from storage tanks to the reactors, during the extrusion of the fibers, and during the stretching, washing, and drying phases of the fiber production process. The latter operations result in continuous release of residual monomer to the ambient air and into process water, as well as into employee work areas.

Methods which will be used by employers to control worker exposure to AN include eliminating and controlling fugitive emissions at tank farm, loading, storage, and reaction areas; ventilation of monomer storage, sampling, and fiber production areas; and enclosure of extrusion, stretching, washing, and drying operations. As with the monomer production industry, spills and leaks of AN would be washed with water into process sewers for treatment and disposal.

None of the exposure control methods cited above will result in an increase in the release of AN into the environment. It should be noted that the amounts of residual AN present in the fibers and released during processing are very small. Thus, although these small amounts are important from the standpoint of employee protection, controls will not involve removal of vast quantities of AN from the general environment. Further, the industry has chemical sewers already installed for the disposal of process wastes and spilled materials, and, therefore, the washdown practices used for control of exposures should not affect waste water disposal practices already in effect.

ABS/SAN resin production. Employees in the ABS/SAN resin manufacturing sector are exposed to AN primarily from latexes containing residual and unreacted AN monomer which are transported throughout the manufacturing process. The highest potential exposures occur around the flocculation tanks, but other major exposure areas include the filtering, washing, and drying processes. As with acrylic fiber production, exposures may also occur when AN monomer is transferred to or from storage tanks and reaction vessels. Methods which will be used to control employee exposures include additional enclosure of processes or operations, ventilation of storage and process areas, washdown of spills, and control of leaks to prevent exposure to fugitive emissions. Further, additional stripping of monomer from intermediate polymer materials may be necessary.

The only control method which has the potential for increasing the total amount of AN released into the environment is stripping. The additional amounts of monomer that can be stripped from the intermediate polymers are greatly limited by two factors, however. First, some stripping is already being carried on by ABS/SAN producers; thus, the remaining amounts of residual AN are relatively small. Second, extensive stripping, beyond what is presently being done, can result in degration of the final product, as noted in the discussion of technological feasibility elsewhere in this preamble. Where additional stripping may be feasible, the amount of AN released from the ABS/SAN materials is expected to be significant only from an employee exposure standpoint (i.e. employee exposures will be reduced), and will not result in large quantities of AN being released into the general human environment.

Stripping is usually performed at an early stage in the polymerization process. The reason that a company strips its polymer products is to assure that residual monomer is not released to expose employees during later stages in the process. It can be assumed, therefore, that much of the monomer which is driven off by stripping would otherwise have been released by the polymer at some point during manufacturing. To this extent, stripping does not increase the total amount of AN released into the environment, but rather, removes at an early stage concentrations of AN which would have been released in any event.

None of the control methods is expected to result in an increase in the amount of AN released to the general environment from the ABS/SAN sector. Conversely, although the amounts of AN to be controlled by the additional engineering methods may be significant from the standpoint of employee health, they do not constitute a major decrease in the total amount of AN released into the environment.

Nitrile elastomer production. Employee exposures occur throughout the entire processing operation for nitrile elastomer manufacture, including the polymerization, coagulation, and washing/drying operations. Further, exposures can occur at AN monomer storage and transfer points. Emissions to the general environment presently arise from these same emission sources.

Methods which will be used by employers to control employee exposures include the same procedures to be employed in the ABS/SAN industry, as noted above. Similarly, the nitrile elastomer sector has also implemented controls to some extent, as have the other industry sectors. Some stripping is already being performed, and further stripping is limited by the same factors present in the ABS/SAN industry.

The controls envisioned for nitrile elastomer production are not expected to result in any significant environmental impacts.

2. At the time that the proposal was published, it was thought that much additional stripping might be feasible for employers in achieving exposure limits below 2 ppm. As we have noted in our discussion of technological feasibility, we have since determined that the type of stripping necessary in the ABS/SAN and nitrile elastomer industries to reach a 1 ppm exposure limit cannot presently be considered feasible. The reasons for this determination were twofold. First, the materials to be stripped have a tendency to coagulate prematurely, and can severely clog the process machinery when further stripping is attempted. Second, stripping which extends much further than present practices can result in severe degradation of the product.

Comments have been received concerning the increased use of stripping, stating that such stripping would release more AN into the ambient air and water, creating an adverse environmental impact. In addition to the reasons expressed with regard to the individual industry sectors, we believe that there are two other bases for our determiniation that there will be no adverse environmental impact from stripping. First, the amounts of residual AN contained in resins and elastomers are usually less than 1 percent by weight. Thus, any amount which can be stripped would be, quantitatively, very small, and, therefore, environmentally insignificant. In addition, of the small amount released, it is assumed that at least some of it would have been released at some later stage of the process if not for the stripping. Second, it is likely that employers

would make efforts to recover and recycle the stripped AN monomer if the amounts were sufficient to make recycling feasible.

3. Several commenters have stated that the proposed standard's requirements for waste disposal would result in a complicated change to current waste disposal practices, and, thus, an adverse environmental impact. No supporting data on this subject were provided in support of this position, however.

OSHA does not believe that the proposed standard, if implemented as written, would significantly increase the amount of solid waste for disposal by AN affected employers, nor would ultimate disposal of AN-contaminated waste be significantly affected. The sole purpose behind the proposed requirement to inclose AN wastes was to eliminate uncontrolled employee contact with AN. Provided that employees charged with further handling of waste materials were properly protected, the standard included no specific requirements for methods of disposal once the waste materials were packaged.

As noted elsewhere in this preamble, we have revised the waste disposal provisions for the final standard removing the requirements for placing AN and PAN waste in closed containers. The reasons for this change are not based upon any adverse environmental impact, but rest upon two basic determinations as to the risk of employee exposure posed by these materials. "PAN scrap," in and of itself, does not constitute a source of AN exposure unless it contains sufficient residual AN. In addition, packaging of materials containing AN can result in a high concentration of AN within the container, thus posing a greater potential for exposure of employees handling the packages for disposal or further treatment. The waste disposal provisions as revised require decontamination by water washdown, ventilation, or other means, before disposal. The revised provisions incorporate continued use of established methods of handling and treating waste materials, while minimizing the risk of AN exposure among employees and other persons handling the materials. Because established methods currently in use are to be continued, the waste disposal section of the final standard does not result in any increased release of AN into the environment.

4. One area of concern to some commenters involved the fact that the Environmental Protection Agency (EPA) was studying emissions from the AN monomer production industry. It was contended that this indicated a community health problem with AN, and that OSHA was remiss in not preparing an EIS to discuss the proposal's impact on this problem. It is true that EPA has conducted extensive studies of air and water emissions from AN production facilities (6,7,8). These studies were prompted by the fact that AN is one of the highest volume organic intermediates produced in this country. Because of the size of the production operations involved and the known toxicity of AN, EPA has been examining the extent of pollutant release into the environment from AN monomer manufacturing facilities.

Findings published by EPA and referred to in the preamble to the proposal have indicated that a number of hazardous air and water pollutants are emitted from AN manufacturing, such as carbon monoxide, hydrocarbons, nitrogen oxides, and sulfur oxides, but that the actual amounts of AN emitted (the only substance to be regulated under the OSHA proposal) are relatively small. EPA is attempting to develop standards and control methods to limit overall exposures to the high volume pollutants contained in the AN industry emissions.

As an example, EPA has found that uncontrolled ground level concentrations from AN manufacturing reach their highest levels in the product storage areas (tank farms). The highest uncontrolled emissions of AN recorded in these areas were less than 0.1 ppm in 24 hours. This level was determined using the assumption that all sources were continuous when, in fact, the actual emissions from storage tank areas are intermittent and probably lower than the 0.1 ppm level. All other point sources of AN emissions are considerably lower than those from the storage area.

5. The use of engineering methods such as exhaust or dilution ventilation will require the increased use of energy in certain segments of the AN industry. Projected energy increases were estimated by Enviro Control, Inc., in the technology assessment and economic impact statement it prepared for OSHA in February 1978. According to this document, annual energy increase (in terms of barrels of No. 6 fuel oil) would be approximately: 131, 323 for the 2 ppm alternative PEL, 222, 150 for the 1 ppm alternative and 312, 591 for the 0.2 ppm alternative PEL.

It was argued by industry representatives that the figures for the 1 ppm and 0.2 ppm levels were underestimated, because compliance by means of dilution ventilation would require more than 40 changes of room air per hour and the Enviro figures did not account for this. Enviro stated that it felt that achievement of compliance by such methods would be impractical and unworkable so it did not estimate the costs associated with such.

It is not anticipated that the increase in energy consumption as a result of this standard will result in significant environmental impacts.

Conclusions. Examination of the environmental impact potential of the proposed standard for control of occupational exposure to AN indicate that the effects of the proposal on the general human environment will not be significant, and preparation of an environmental impact statement is not required.

REFERENCES: ENVIRONMENTAL IMPACT

1. Ex. 11:(27).
2. Ex 160.
3. Exs. 11:(18); 155.
4. Ex. 11:(13).
5. Exs. 11:(22); 71.
6. Horn, D. A. and T. W. Hughes. Source Assessment: Acrylonitrile Manufacture (Air Emissions). Monsanto Research Corp. EPA-600/2-76-032. Environmental Protection Agency. March 1977. 98 pp.
7. Schwartz, W. A., F. B. Higgins, Jr., J. A. Lee, R. Newirth, and J. W. Pervier. Engineering and cost Study of Air Pollution Control for the Petrochemical Industry, Vol. 2: Acrylonitrile Manufacture. Houdry Division, Air Products and Chemicals, Inc., EPA-450/3-73-006-b, Environmental Protection Agency, February 1975.
8. Lowenbach, W. and J. Schlesinger. Acrylonitrile Manufacture: Pollutant Prediction and Abatement. Mitre Technical Report MTR-7752, prepared under Contract No. 68-01-3188 with the Environmental Protection Agency, February 1978.

SUMMARY AND EXPLANATION OF THE STANDARD

The following sections discuss the individual requirements of the AN standard. The sections include an analysis of the record evidence and the policy considerations underlying the decisions as to the various provisions of the standard. As discussed in the PEL section above, the final standard sets a permissible exposure limit for acrylonitrile of 2 ppm as an 8-hour TWA, with a ceiling limit of 10 ppm as measured over any 15-minute period during the workshift. Engineering controls and work practices are required where necessary to reach the PEL, and written compliance plans must be developed. Engineering controls must be in place by November 2, 1980, or 2 years from the effective date of the standard. Other portions of the standard including those on respirators, protective clothing, hygiene facilities, exposure monitoring, and the exemption provisions have been revised and clarified as described in detail below.

The language of the standard and the order of the various provisions is consistent with the drafting in other recent OSHA health standards, such as the benzene final standard (43 FR 5913) and the arsenic final standard (43 FR 19584). OSHA believes that a similar style should be followed from standard to standard in order to lead

to uniformity of interpretation of similar provisions. Section 6(b)(5) of the Act states that health standards shall also be based on "experience gained under this and other health and safety laws."

Scope and application: Paragraph (a). This standard applies generally to all occupational exposures to acrylonitrile (AN). Some of the industry sectors where significant exposures to AN may occur are in the manufacturing of AN monomer, the production of acrylic/modacrylic fibers, and in the polymerization of AN with other monomers to produce resins, elastomers, and other materials. It should be noted, however, that not all workplaces where AN may be found will be subject to the AN standard. OSHA has determined that the standard should be focused towards those workplaces in which there is the greatest potential for AN exposure. This would involve primarily the manufacturers of AN, the manufacturers of acrylic and modacrylic fibers, and producers of ABS and SAN resins, nitrile elastomers, polymer polyols, and other AN based polymers and materials. In a limited number of cases, downstream processing, handling, and use of certain materials made from or containing AN will be covered by the standard.

The exemption provisions of the final standard contain both a listing of materials which are exempted, and two performance bases upon which materials not specifically listed can be exempted. The exemptions as drafted differ markedly in several respects from those in the proposal. A detailed discussion of the changes that have been made and the rationale for these changes are contained elsewhere in the preamble to this standard.

The first exemption provision, paragraph (a)(2)(i), lists a number of "finished polymers" which are to be exempted from the AN standard. This listing reflects the data received in the record which shows the minimal potential for AN exposure to employees during further processing, use and handling of these materials. The term "finished polymers" is not defined in the standard. This is because it is not possible to state as a general matter the area of the manufacturing at which each polymer listed becomes "finished." In most cases, this involves a drying step, after which the polymers are packaged and/or stored. At this point, the polymers are no longer being "manufactured." Further handling, including shipping, processing and use, of the finished polymers, is exempt from the standard.

As is the case with most polymers, which contain some amounts of residual monomer, some of the AN based polymers on the exempted list may release monomer into the headspace at the top of their storage vessels. When the vessels are opened, the monomer escapes, with the potential of exposing employees to AN. OSHA recognizes that this can and will occur. However, the resultant low level exposures are transient and do not represent a significant source of exposure. (It should be noted that other materials not listed in paragraph (a)(2)(i) may exhibit this phenomenon as well. If the materials would otherwise qualify for exemption under the performance criteria in (a)(2)(ii) for TWA exposures, the headspace release will not affect their exemption.)

Paragraph (a)(2)(ii) carries forward, with minor modifications, the performance criteria provided in paragraph (a)(2)(i) of the proposal. The criteria are applicable to all materials made from and/or containing AN. This clarifies a problem area from the ETS and proposal, which referred only to "products fabricated from PAN." OSHA's interpretation of the ETS has been that PAN itself and other materials made from AN should be allowed an exemption if they meet the performance criteria for AN release.

The criteria for exemption under paragraph (a)(2)(ii) involve the providing of and reasonable reliance on objective data showing the following: that the material is not capable of releasing AN resulting in airborne concentrations exceeding 1 ppm (as an 8-hour TWA) under the expected conditions of processing, handling and use which will cause the greatest possible release. OSHA anticipates that the manufacturer of the material will be in the best position to test his products and supply the necessary objective data.

The "1 ppm release" referred to in the exemption as proposed meant an 8-hour time-weighted average under expected conditions involving the greatest possible release of AN. The Agency has interpreted the ETS in this manner, and is revising the final standard to refer explicitly to an 8-hour TWA.

The third exemption provision, paragraph (a)(2)(iii), exempts the handling, use, and processing of solid materials made from and/or containing AN if they are not heated above 170° F. This is changed from the proposal to set a temperature limit instead of the term "heating or melting." This provision is included primarily to cover future products made from AN, since most solid materials are already exempted by the listing in paragraph (a)(2)(i). The term "solid materials" is meant to clarify that the exemption (paragraph (a)(2)(iii)) does not apply to liquid AN, as defined in the standard.

Action level. The proposal contained alternative action levels of 1 ppm, 0.5 ppm, and 0.1 ppm, corresponding to the three alternative PEL's of 2, 1 and 0.2 ppm, respectively. The action level triggers the monitoring and medical surveillance requirements of the proposal. The final standard sets an action level of 1 ppm, in accordance with the 2 ppm PEL.

The record contains little negative comment on the action level concept. Most comments received were directed at the various PEL's, and addressed the action level primarily from the measurement and monitoring standpoint (Exs. 92; 11:(14)).

In the absence of a demonstrated safe level of exposure for a carcinogen, OSHA has consistently required that employee exposure be limited to the maximum extent feasible by the use of engineering controls and work practices. OSHA believes that it is also appropriate to begin some protective actions under the standard prior to exceeding the PEL. The action level serves such a purpose. Another purpose of the action level is to help to relieve the burden on employers by providing a cut off point for many of the required compliance activities under the standard.

From a pure health viewpoint, it would not be unreasonable to require some action to be taken wherever employees may be exposed to a carcinogen. However, this approach would be unduly burdensone both to the affected employers and to the Agency. Nonetheless, the standard necessarily will encompass some employers whose employees are exposed below the PEL. We expect that the exemption provisions will greatly limit this group of employers. Where they are covered, such employers are required to perform initial monitoring to determine the extent of their employees' AN exposures. If, on the basis of the initial monitoring results, an employee's exposure is below the action level, the employer may discontinue monitoring and all other compliance activities for that employee except for training and labeling. The action level concept thus provides an objective means for an employer to determine what further actions are required for compliance with the standard.

The statistical basis for determining the action level has been discussed in connection with several proposed OSHA standards (see, for example, "Proposed Standard for Trichloroethylene" (Oct. 20, 1975, 40 FR 49032)). In brief, although all measurements on a given day may fall below the permissible exposure limit, some possibility exists that on unmeasured days, the employee's actual exposure may exceed the permissible limit. Indeed, as various parties have noted, the ex-

posures in the AN industry can vary widely from day to day. Where exposure measurements are above one-half of the permissible exposure limit, i.e., the action level, the employer cannot reasonably be confident that his employees may not be overexposed. (Leidel, N.A. et al., "Exposure Measurement Action Level and Occupational Environmental Variability," DHEW, PHS, DCD, NIOSH, DLCK (August 1975)). Therefore, requiring periodic employee exposure measurements to begin at the action level provides the employer with a reasonable degree of confidence in the results of his measurement program.

Definitions: Paragraph (b). For the purposes of the final standard, "decontamination" means treatment of liquid AN waste, protective clothing, work surfaces, and other areas, usually by means of ventilation or water washdowns, to assure that the materials or surfaces no longer release AN above 1 ppm. Unlike the exemption provisions, the decontamination provisions deal with actual release of AN from a leak, spill, or other source of liquid AN, rather than with the potential for release from a material during processing. Testing to assure nonrelease from a decontaminated area, therefore, may be performed by an area sample, provided that the probe is placed at least as close as any employee would get to the point of AN release.

The term "emergency", as used in the proposal, covered any release of AN above the ceiling limit. The breadth of this definition would have required the employer to implement the emergency procedures and notify the OSHA area office whenever the ceiling was exceeded. As was noted by several commentators, such a requirement would apply to many situations which could not truly be deemed as "emergencies" (Exs. 92; 149). In addition, we recognize that this would tend to lessen the employee's awareness of true emergency conditions if and when they did occur.

"Emergency" has been redefined, as in the vinyl chloride standard, to refer to a "massive release" of AN. The employer is best able to determine if an emergency exists in his facilities. His central obligation under the standard, which is to limit employees' exposures to AN, is, therefore, supplemented by the requirement to take further action when emergency situations arise.

The proposal defined "polyacrylonitrile," or "PAN" for the purposes of the standard, as homopolymers or copolymers made from AN except for materials exempted under paragraph (a)(2).

This proposed definition of "PAN" has been deleted from the final standard for several reasons. The standard was and is intended to protect employees from exposure to AN monomer. There is nothing to indicate that polyacrylonitrile itself is harmful, other than through its release of residual quantities of AN. In addition, the definition of "PAN", as proposed, led to some confusion under the ETS. Whereas the proposed standard was to apply only to PAN as limited in the definition (not to all generic polyacrylonitrile materials), some persons thought that references to "PAN" throughout the proposed standard meant all polyacrylonitrile materials, regardless of potential for AN release and exposure.

The standard has been revised to read solely in terms of "AN" and "liquid AN." As noted in the discussion of the scope of the standard, the processing, use and handling of most "PAN" materials have been expressly exempted from the standard. The performance exemption has also been modified accordingly, to allow materials made from or containing AN to be exempted if they meet the conditions set forth in paragraph (a)(2)(ii). The use of the phrase "products fabricated from PAN," as contained in the proposed exemption was too restrictive, since it did not, on its face, appear to allow PAN itself or other materials made from or containing AN to qualify for exemption.

A new definition for "liquid AN" has been added to the final standard. This definition is intended to assure that all intermediate products of the polymerization process are covered by the standard. The definition also provides a differentiation between intermediate latexes and other liquid polymer intermediates created in ABS/SAN and nitrile rubber manufacturing, and final product latexes. Whereas final product latexes may present an AN inhalation problem in some cases, there is nothing to indicate that they also pose a significant potential for skin exposure to AN. The skin and eye contact provisions, along with the concomitant protective clothing and equipment provisions, have therefore been drafted in terms of "liquid AN" monomer and polymer intermediates.

Exposure monitoring and measurement: Paragraph (e). The standard requires each employer who has a place of employment where there is exposure to AN as the result of the employer's activities (except where exempted under paragraph (a)(2)) to monitor his employees' exposure to AN, and to determine an employee's exposure over an 8-hour period without regard to the use of respiratory protection. Section 6(b)(7) of the Act (29 U.S.C. 655) mandates that any standard promulgated under section 6(b) shall, where appropriate, provide for monitoring or measuring employee exposure at such locations and intervals, and in such manner, as may be necessary for the protection of employees.

There are various reasons which make it appropriate for employers to measure employee exposure to AN. First, exposure monitoring informs the employer as to whether he is meeting his legal obligation to keep employee exposures below the permissible exposure limit. Second, exposure monitoring evaluates the effectiveness of the installation of engineering and work practice controls and informs the employer as to whether additional controls need to be instituted. Third, exposure monitoring is necessary in order to determine whether respiratory protection is required at all, and if so, which respirator is to be selected.

Fourth, section 8(c)(3) of the Act (29 U.S.C. 657) requires employers to notify promptly any employee who has been or is being exposed to toxic materials or harmful physical agents at levels which exceed those prescribed by an applicable occupational safety or health standard, and to inform such employee of the corrective action being taken. Exposure monitoring is necessary in order to determine whether employees are being exposed to AN at levels exceeding that prescribed by this standard and therefore must be notified as required by the Act. Finally, the results of exposure monitoring are part of the information which must be supplied to the physician.

The need to conduct exposure monitoring was generally accepted by participants in the rulemaking proceeding. A major point of contention centered on the available methods of sampling and analysis, as discussed below. In addition, several employers noted that they already conducted monitoring on a more frequent basis than the monthly and quarterly periods included in the proposal (Exs. 11:(25); 11:(27)). They contended, however, that the standard should only require employee notification of the required qurterly or monthly monitoring. The wording of the proposal, in their view, would have required the employer to notify the employee of any additional monitoring results that he might have as a result of more frequent monitoring. It was argued that to require notification of extra monitoring results would discourage employers from conducting more frequent monitoring than that required by the standard.

Section 8(c)(3) of the Act (29 U.S.C. 657) requires employers to notify promptly all employees exposed above the PEL. The final standard implements section 8(c)(3) by requiring an employer to notify each employee in writing of the employee's measurement within 5 working days after the

receipt of the results of any required measurements.

OSHA recognizes that the standard is intended to set only minimum monitoring requirements for employers. It is reasonable, then, that the standard should only require the notification to employees when monitoring required by the standard is carried out. Additional actions by the employer in monitoring exposures, while certainly encouraged by OSHA, are not required by the standard, and direct notification need not be given to employees.

The standard requires that measurements be made by monitoring which is representative of each employee's exposure to AN over and 8-hour period without regard to respiratory protection. Exposure measurements for each individual employee would, certainly, be an indication of that employee's exposure. However, this may be unnecessarily burdensome in some instances. Monitoring which can be shown to be representative of an employee's exposure would provide the necessary information and in many instances would require fewer samples. This is particularly true in manufacturing of AN and other 24-hour continuous processes.

The proposal required monitoring monthly for employees exposed above the permissible exposure limit and quarterly for employees exposed between the action level and the PEL. As noted above, many employers have indicated that they perform monitoring on a more frequent basis. It is evident that the higher the frequency of measurement, the higher the accuracy of the employee's exposure profile. The companies involved with the manufacturing and polymerizing of AN indicated little, if any, disagreement with the monitoring frequency in the proposal. OSHA has carried forward these provisions to the final standard. We believe that in the industries affected by this standard, monthly and quarterly monitoring will reflect employee exposure with sufficient accuracy to assure that suitable precautions will be taken as needed to protect employees from exposure to AN.

Industry representatives have concentrated much of their criticism on what they have contended to be the lack of a method of sampling and analysis for AN in the range of 1 ppm and below which will meet the accuracy and precision requirements set forth in the proposed standard. This issue was brought to the surface by the original NIOSH recommendations in September 1977 (Ex. 65). In those recommendations, NIOSH stated that OSHA should issue a 4 ppm standard, based upon what they characterized as the limitations of existing sampling and analytical methods for AN. As we pointed out at length in the preamble to the ETS, OSHA was most concerned about this situation, particularly in light of the industry recommendations at that time that the standard be set as low as 2 ppm. Therefore, testing was performed at the OSHA Analytical Laboratory in Salt Lake City, Utah, to determine whether NIOSH method S-156, which was the method used under the existing 20 ppm standard, could also be used in sampling lower concentrations (see appendix D).

The test results clearly showed that S-156 could be used for sampling and analysis below 1 ppm with sufficient accuracy (Exs. 18; 18A). Testing was performed in the presence of high humidity (85 percent) and other monomers, such as styrene and butadiene, to determine whether these elements had any detrimental effect on the sampling and analysis. The effects of these factors was negligible. The Director of the OSHA Laboratory, Floyd Madsen, appeared at the rulemaking hearing and was questioned at length by industry representatives concerning his testing procedures and results. In addition, representatives of SPI were permitted to visit the Laboratory after the hearing, in order to talk with Mr. Madsen further concerning sampling and analysis, in response to a direct request at the hearing by both SPI and Vistron. Although such a visit did, indeed, go beyond what is required of the Agency during informal rulemaking, OSHA determined that it was, in this limited circumstance, an appropriate gesture toward developing a complete record on the sampling issue.

Laboratory testing has also been performed by NIOSH at their laboratories in Cincinnati, also involving method S-156. Data submitted to the record by Dr. Judd Posner of NIOSH also demonstrated that AN could be sampled and analysed below 1 ppm with accuracy (Exs. 43; 66). Since this data was submitted during the course of the hearing, Dr. Posner invited interested persons at the hearing to submit questions to him in writing, to which he would reply during the post-hearing comment period. It is important to note that no such questions were received. A complete write-up of the analytical method and sampling technique used by NIOSH is available in the record (see appendix D). In essence, it sets forth the same method utilized by the OSHA Laboratory, with the major exceptions being the use of a different desorbing solvent and the use of flame ionization without the nitrogen phosphorus detector.

OSHA does not require that any one specific method of sampling and analysis be used for compliance with the monitoring provisions of the standard. This provision is set forth in performance language, and permits the use of any method which meets the accuracy and precision requirements set forth therein. The testing that OSHA has performed, supplemented by the NIOSH data, serves to demonstrate that there is at least one method available which meets those requirements. We are fully aware that there are many other methods in use throughout industry to sample for AN, as well as methods which are in varying stages of development. Such methods include the use of porous polymer tubes instead of charcoal tubes for collecting the sample, gas bags, badge-type dosimeters, and the use of portable and fixed-point sampling devices and systems. Considerable data has been submitted to the record by many companies concerning their experience with these methods. By demonstrating the availability and effectiveness of S-156 as modified, we do not intend to short-circuit any of the efforts by these companies to develop their own monitoring procedures, some of which may prove to be even more accurate.

Industry representatives have argued that it is essential for a method to be "field validated" in order to be used for compliance with the AN standard (Exs. 75; 83). Yet it should be noted that such representatives have also stated that the range of field conditions that may be encountered in the AN industry is so wide and variable that it would be necessary to "field validate" a method in each individual workplace in order to show that it was, indeed, a workable method across the board (Tr. 933). It is evident that no single analytical method will work in every imaginable workplace situation, either for AN or for most any other organic vapor. In addition, it is also clear that whatever method an employer may choose to use to monitor for AN, he must validate it for use in his particular plant. The need for such individual validation was espoused by industry representatives (Tr. 933).

The method of "field validation" proposed by Dr. Ward of Monsanto presents an interesting approach which shows promise (Ex. 136). However, there is nothing to indicate that a method is or has been in use in the past to "field validate" sampling methods for AN or other organic vapors. In addition, Dr. Posner of NIOSH has submitted an analysis of Dr. Ward's validation method which points up that it, too, is not without pitfalls in its implementation (Ex. 140). There is no single accepted method of "field validating" a sampling method to obtain data which will support its use under all workplace conditions.

A detailed exposition of the range of available methods of sampling and analysis for AN was contained in the written comments submitted by Monsanto (Ex. 11:(27)). Table A contains a

listing of five methods which were either validated by Monsanto (field and/or laboratory validation) or, in the case of the gasbags, showed a detection limit below 1 ppm. The field validation was, presumedly, carried out under the protocol submitted by Ward (Ex. 136). Although Monsanto reported difficulty in using NIOSH method S-156, it is clear that they have been able to develop or apply other methods of sampling and analysis to their many and varied operations.

Monsanto, in their written comments, discussed the various problems that they had experienced with NIOSH method S-156 (Ex. 11:(27)). They noted that the only charcoal lot which had shown satisfactory results was lot 107. This point was noted by Madsen in his testimony (Tr. 132). In dealing with the problems of sample "breakthrough" reported by various companies, including Borg-Warner (Ex. 83), Monsanto noted that some companies are using two larger charcoal tubes, containing up to 1,000 mg., in series, to replace the 150-mg. tubes generally used. They have concluded, however, that there is no evidence of any effect of humidity or temperature at low AN burden.

Monsanto noted that charcoal tube methods can be used for AN at concentrations below 2 ppm even where AN recovery (with methanol or carbon disulfide) falls below 75 percent by developing a "working curve," in lieu of the NIOSH protocol. They emphasized that appropriate validation techniques are necessary for the use of all monitoring procedures in the workplace setting, whether charcoal tubes or other means of sampling are used. They have chosen to rely upon alternative systems, such as porous polymer adsorption/thermal desorption, since they consider them to be less subject to the types of variables associated with charcoal-based systems.

As was noted by Madsen in his testimony at the hearing, Monsanto concurs that the use of a nitrogen-specific gas chromatographic (GC) detector has the potential of enhancing the detection limit of all of the methods listed in the table by a factor of 10 (Ex. 11:(27)). It is also important to note that other methods which involve gas chromatographic analysis, have this same potential.

Monsanto has also reported using both the Century QVA 128 and Century flare tubes at levels well below 1 ppm, noting only that "the methods are claimed to be selective." Century Systems testified independently that their instrumentation was capable of measuring AN at concentrations well below 1 ppm as an 8-hour TWA (Tr. 873-874).

TABLE B: ADDITIONAL METHODS OF MONITORING AND ANALYSIS

FOR AN BELOW 1 PPM

(Adapted from Monsanto comments (Exhibit 11:(27)))

	Method	Adsorption/Desorption/ Analysis	Validation: concentration, detection limits
1.	Monsanto PoropaK-N	Poropak-N (porous polymer)/Thermal/GC	field validated down to 0.1 ppm; detection limit approaching 0.02 ppm for a 3-liter air sample.
2.	Modified NIOSH P&CAM 127	Charcoal/1 to 2% Acetone in CS_2/GC	field validated at levels above 0.08 ppm within ± 2 std. devs. for a TWA_6.
3.	NIOSH P&CAM 127	Charcoal/CS_2/GC	laboratory and field validated at and above 0.2 ppm for a TWA_6; Reported loss of AN when desorbed sample is stored over time.
4.	Passive Dosimetry	Abcor R Gasbadge/Acetone in CS_2/GC	laboratory validated 0.94 ppm; field tested at 0.8-3.8 ppm by reference to method no. 2 above.
5.	Gas sample bags	Gas bag/GC	Detection limit of ca a 2.5 cc. gas sample. Reported memory effects at low AN levels.

Monsanto was confident that "the charcoal tube or passive dosimeter methods could be practiced by downstream processors with some guidance from trained professional" (Ex. 11:(27)). The record reflects that the employers covered by this standard possess considerably more technical capability in this area than downstream employers would be expected to have. The broadening of the exemption provisions will limit the scope of the standard to those companies best able to provide an effective monitoring program which will produce meaningful results.

Companies such as Goodyear, Dow Badische, and Dow Chemical have submitted details of the sampling and analytical methods that they have found valid for use in their respective operation (Exs. 138; 11:(17); 11:(25)). Still others have installed continuous monitoring systems which provide area measurements of airborne AN concentrations (Exs. 11:(10); 11:(8)).

As the record makes clear, there are a number of adequate methods available for sampling and analysis of AN concentrations at and below 1 ppm. OSHA recognizes that one method may not work under all workplace conditions due to such variables as temperature, humidity, and other unique factors. Regardless of the method selected, an employer must validate the method that he intends to use under the conditions present in the particular workplace to assure himself that it will be sufficiently accurate. It is for this reason that the monitoring accuracy and precision required by the standard are stated in performance terms. The OSHA and NIOSH methods of monitoring employee exposures are included as an appendix to the final standard as a means of assisting the employer in the selection of an appropriate method for his workplace.

It was also contended that because neither the OSHA nor the NIOSH variations of method S-156 had been "field validated" under all workplace insults and exposure conditions, they could not serve as reference methods. This assertion totally misconstrues the true purpose of a so-called "reference method." The applicability of any "reference method" was described most accurately at the hearing by Dr. Ward:

> There is always a need for a reference method. However, the reference method cannot serve under all applications. It can serve under laboratory conditions and it has merit in that respect * * *. (Tr. 791).

OSHA and NIOSH have both performed laboratory testing of their variations of NIOSH method S-156 and have found the method to be a suitable reference method for use in the range of concentrations covered by the standard (Exs. 18; 18A; 43; 66).

The monitoring defined by the OSHA Laboratory involves the use of charcoal tubes and personal sampling pumps, with subsequent analysis by gas chromatograph with nitrogen phosphorus detector. Laboratory validation data indicates that this method can be used with sufficient accuracy and precision down to the 0.5-ppm level and below. Floyd Madsen was questioned extensively at the hearing as to his findings by industry representatives (Tr. 117-159). In addition, several industry personnel visited Madsen at the Laboratory during the posthearing comment period (Ex. 142). Neither the questioning at the hearing nor the laboratory visit have raised any significant questions as to Madsen's findings.

The primary differences between the NIOSH and OSHA variations on S-156 are the method of desorption (NIOSH does not use ultrasonic agitation of the sample), the desorbing solvent (NIOSH use 1 percent acetone in carbon disulfide, whereas OSHA uses methanol), and the analytical equipment (NIOSH uses flame ionization, whereas OSHA adds a nitrogen-phosphorus detector).

Method S-156 and variations thereon have been adopted and accepted for general use in field monitoring at the 1- to 2-ppm level by several major companies that manufacture and/or use AN in their facilities. Workplace conditions and other factors vary widely among these companies (cf. Ex. 2:(22); 11:(14); 138; Tr. 1196-1199).

The standard requires that the measurements be made by monitoring which is representative of each employee's exposure to AN over an 8-hour period without regard to the use of respiratory protection. Exposure measurements for each individual employee would, of course, be an indication of that employee's exposure. However, this may be unnecessarily burdensome in some instances. Monitoring which is truly representative of an employee's exposure would provide the necessary information and in many instances would involve fewer samples.

In their testimony, the NIOSH panel expressed concern that OSHA did not specify a means of determining if an exposure measurement was "representative" of an employee's exposure. They believed that this presented a potential for actually reducing the protection afforded to workers exposed to AN. OSHA believes that the standard should require the desired performance, i.e., a showing of representativeness, rather than specifying one method for determining it. We recognize, however, that NIOSH has published a document outlining a sampling strategy which is directed at this problem (Ex. 14:(157)). That strategy is certainly one approach toward determining representativeness of exposure measurements. There are other approaches which would be suitable, as well. The employer has the burden of showing, by whatever means at his disposal, that his measurements are representative of each employee's exposure to AN.

The rulemaking record, along with experience under the ETS, indicate that most affected employers have successfully implemented a monitoring method which gives satisfactory results in their operations, at concentrations in the 1- to 2-ppm range. However, OSHA cannot ignore the difficulties that various companies have reported in demonstrating the required accuracy and precision specified in both the ETS and proposal at a (95 percent confidence level, ±25 percent at or above 2 ppm, and ±35 percent below 2 ppm) (Exs. 83; 159). We have determined that these criteria should be made more flexible, in order to assist employers who have encountered unique sampling problems. Therefore, the final standard permits the use of methods with accuracy and precision at a 95-percent confidence level, of ±35 percent at or above 2 ppm, and ±50 percent below 1 and 2 ppm. The difference (35 percent vs. 50 percent) reflects a recognition that accuracy of monitoring decreases below 2 ppm.

The accuracy and precision requirements are intended to provide the employer with a degree of confidence in his sampling results. As noted earlier, monitoring is not carried out for its own sake, but for the purposes of determining what is required for compliance in a given operation. OSHA anticipates that the wide range of available methods, combined with more flexible criteria for the method employed, will enable employers to perform their required monitoring without serious difficulties.

The employee exposure measurements are to be made without regard to the use of respiratory protection. One commentator took issue with this provision, contending that the sampling does not reflect the actual exposure of the employee who is being protected by a respirator (Ex. 149). Whereas this statement may be true, it overlooks the fact that exposure monitoring is not a single-purpose activity. It is necessary to know employee exposure levels without the use of respiratory protection in order to evaluate the effectiveness of the required engineering and work practice controls, and to determine whether additional controls must be instituted. In addition, monitoring is necessary to determine which, if any, respirator must be used by the employee.

As noted by numerous participants in this rulemaking proceeding, exposure conditions vary throughout the day in many operations. At least one sample is to be taken during each shift in order to assure that exposure measurements represent exposures of employees on all shifts. Employees working in the same area doing different jobs may have different exposures. Therefore, the standard requires sampling for each job classification, as well. The proposed standard did not contain detailed procedures in this regard. However, in order to assure accurate representative monitoring of employee exposures, OSHA has determined that the variability of exposures warrants such procedures.

The standard requires that the initial monitoring be conducted, and the results thereof obtained, as of the effective date of the standard. OSHA believes that this provides more than enough time for employers to complete the sampling and obtain the results. Moreover, the standard permits employers who have monitored under the ETS, or since January 17, 1978, to utilize these measurements for purposes of complying with the initial monitoring requirements of the final standard. Employers who have already monitored their employees' exposures within this period will, therefore, not have to conduct initial monitoring unless, because of a process, control, or personnel change, they are required to redetermine exposures.

The final standard requires measurement every 3 months for employees exposed between the action level and the TWA limit, and monthly for employees exposed above the TWA limit.

The higher the measurement frequency, the higher the accuracy of the employee exposure profile. The selection of an appropriate interval between monitoring efforts is judgmental. OSHA has determined that requiring monthly and quarterly monitoring for AN exposures will reflect employee exposure with sufficient accuracy to assure that suitable precautions will be taken as needed.

Periodic measurement is appropriate when exposures are in the 1-2 ppm range because of the possibility that minor changes in process, materials, or weather conditions may raise exposure to above the TWA limit, and to compensate for the possibility that such measurements are falsely low.

Periodic monitoring and measurement are not required when initial measurements are below 1 ppm. It is unlikely, when exposures are at this level, that minor fluctuations in process, materials, or weather or measurement accuracy would result in false negative readings below the TWA limit. It would not be appropriate to require periodic measurements in those operations where exposures would be well below the permissible exposure limit.

The standard requires that whenever there has been a production, process, or control change which may result in new or additional exposures to AN, or whenever the employer has reason to suspect an increase in employee exposure, the employer shall repeat the required monitoring and measurements for those employees affected by such change or increase.

The redetermination procedure is necessary to assure that the most recent monitoring results accurately represent the existing exposure conditions. This is necessary so that the employer may take appropriate actions such as instituting additional engineering controls and providing appropriate respiratory protection.

The final standard also provides that employers may discontinue periodic monitoring for those employees for whom two consecutive measurements, taken at least 7 days apart, show exposures to be below the action level. Where employee exposure measurements fall below the permissible exposure limits but are at or above the action level, the employer may alter the monitoring schedule for those employees from monthly to quarterly after two consecutive measurements taken at least 7 days apart indicate the reduction in levels.

Section 8(c)(3) of the act (29 U.S.C. 657) requires employers to promptly notify an employee who is exposed in excess of the permissible exposure limit. The standard requires the employer to notify each employee in writing of that employee's measurement within 5 working days after the receipt of the results of any measurements required under paragraph (e). Notification in writing need not be an individual letter to the employee, but may be a notice prominently displayed on a bulletin board or similar workplace location.

OSHA has determined that the proposed paragraph (e)(7), requiring a weekly survey of operations involving liquid AN, should be deleted from the monitoring provisions of the final standard. The data in the record indicates that the purposes of the weekly survey (i.e., detection of leaks and spills of liquid AN) can be achieved through a less elaborate and detailed leak detection program.

The unpredictable nature of fugitive emissions from valves, pumps, and the like, makes it unlikely that a survey performed on a weekly basis will detect all, or even most, of the leaks and spills that occur in liquid AN operations. Further, such a weekly survey would add little to the exposure monitoring required by the standard, in determining employee exposure to AN.

The alarm system required by paragraph (i) of the standard will detect AN concentrations which exceed the ceiling limit. When an alarm is sounded, the employer will have to take action to locate the source of the release which is causing the high levels of AN, and will then have to decontaminate the leak or spill area. In this regard, the weekly survey, as proposed, would be redundant.

OSHA has determined, however, that some form of leak detection program should be required by the standard. The details of such a program, however, should be left to the employer, who is already under the obligation to control employee exposures to within the permissible exposure limits. The leak detection program in the final standard has been placed in the housekeeping section of the standard, paragraph (k).

Regulated areas and notification: Paragraphs (d) and (f). The final standard requires the employer to establish regulated areas wherever AN exposures exceed the PEL, and to limit access to these areas to authorized persons. This requirement will help to limit exposure to AN by preventing persons who are not authorized from entering areas with AN exposures above 2 ppm. It will also assist in designating areas where precautionary signs are to be posted, while also designating areas where employees will be subject to monthly exposure monitoring pursuant to paragraph (e). Employees in regulated areas willl be prohibited from smoking and eating in these areas, and may be covered by protective clothing and equipment and hygiene requirements under other sections of the standard.

The limitation on eating, smoking, and applying cosmetics in regulated areas is necessary to prevent unnecessary exposure to AN. Potential routes of exposure to AN are ingestion, skin absorption, and inhalation. All of these routes must be limited by OSHA in order to protect employees from the carcinogenic hazard posed by AN exposure.

Paragraph (d) of this standard requires the employer to notify the OSHA Area Office within 30 days of the establishment of regulated areas in his workplace. This requirement is more limited than was proposed, in order to concentrate on exposure conditions above the PEL. It enables the Agency to be aware of facilities where substantial exposure to AN exists.

Methods of compliance: Paragraph (g). The final standard requires that by November 2, 1980, engineering controls and work practices be used to control employee exposure to acrylonitrile, except to the extent that the employer can show that they are not feasible. If all feasible engineering and

work practice controls do not succeed in reducing exposure below the permissible exposure limit, they must be implemented and supplemented by respiratory protection. OSHA's experience has been that engineering controls must be coupled with suitable work practices to maximize their effectiveness. Respiratory protection may be used only during the time period necessary to install engineering controls, where engineering controls may be inappropriate, such as during some maintenance operations, or in those cases when both engineering controls and work practices do not succeed in reducing exposures below the permissible exposure limit. Respirators are also to be used in emergencies.

This compliance strategy has been consistently OSHA's policy and has been followed in prior standards and proposed standards. This policy is based upon the view that the most effective means of controlling employee exposure is to contain emissions of toxic substances at their source through the use of mechanical means combined with work practices. This is far more effective than reliance on the highly variable human behavior so critical to the successful use of respirators. As discussed below, respirators have many disadvantages which preclude primary reliance or coreliance on respiratory protection on an equal basis with engineering and work practice controls. Furthermore, the burden of reducing employee exposure should more properly rest on the employer in whose establishment toxic substances are released, rather than placing the burden of respirator use on the exposed employee.

The Council on Wage and Price Stability suggested a control strategy involving principal reliance on respiratory protection, to reduce the cost of compliance (Ex. 27). However, the affected companies themselves readily acknowledge the many difficulties inherent in reliance upon respiratory protective devices (Exs. 11:(27); 92). These difficulties were also discussed by respirator expert Darell Bevis (Ex. 19). Because of the difficulties in obtaining and maintaining a proper fit and seal of the respirator facepiece, it is difficult to know whether the respirators actually provide adequate protection. Respirators, by interfering with vision, hearing, and mobility, can cause safety problems. Some employees cannot wear respirators because of breathing difficulties. Finally, it is not appropriate to place the burden of compliance principally on the employee, as would be the case if respiratory protection were the principal means of reducing employee exposure. Therefore, OSHA retains in the standard the policy of principal reliance on engineering controls and work practices, except in circumstances where there is no feasible alternative to more substantial reliance on respiratory protection.

Even in situations in which engineering controls will not succeed in reducing exposure levels below the TWA limit, it is still appropriate to require all feasible engineering controls to be installed, even though they would have to be supplemented by the use of respirators. The engineering controls, by minimizing the amounts of AN in the workplace environment, will also minimize the potential for overexposure to AN resulting from poorly fitting respirators, and will usually reduce the number of employees who will need to wear respirators at all.

The standard places the burden on the employer for proving or disproving feasibility. The employer is in the best position to gather evidence on feasibility in a particular workplace. He is most familiar with his own production processes and engineering modifications which can be made. Further, it is the policy of the OSHA Act that employers be required to take steps to investigate the feasibility of controls and install them as necessary.

In addition to the obligation to institute engineering and work practice controls, except to the extent that such controls are not feasible, the final standard also requires that each employer establish and implement a plan for reducing exposures to within the permissible exposure limits solely by engineering and work practice controls. These written plans must be furnished upon request for examination and copying to representatives of the Assistant Secretary and the Director. These plans must be reviewed and updated periodically to reflect the current status of exposure control. The written plan is an essential part of the compliance program, since it will encourage employers to implement the necessary technology for reducing employee exposures. It also provides the information to allow OSHA, the employers, and employees to examine the control methods chosen and the extent to which these planned controls are being implemented in the workplace.

Respirators: Paragraph (h). The standard requires that respirators be used only during the time period necessary to install or implement feasible engineering and work practice controls, in operations in which such controls are not appropriate, such as certain maintenance operations, in work operations in which such controls are not feasible or are not yet sufficient to reduce exposure to the permissible limits, or in emergencies. These restrictions on the use of respirators are consistent with the requirements of 29 CFR 1910.1000(e) and with good industrial hygiene practice.

Many comments cited problems associated with respirators (Exs. 92; 11(27)). Respirators are to be considered secondary to the objective of limiting emissions at the source. Proper facial fit is essential, but due to variations in individual facial dimensions, as well as facial hair, scars, or growths, it is difficult to maintain. Fatigue and reduced efficiency may occur more rapidly among workers wearing respirators due to increased breathing resistance, heat stress, and reduced vision. Additional problems include the entanglement of hoses of air-supplied respirators, as well as limited mobility resulting from hose length and bulkiness of the apparatus. (Ex. 19).

It is clear, and generally agreed to by the affected employers, that respirators cannot generally be considered as the primary means of employee health protection. It is also recognized by OSHA that there will be certain operations in which the use of respirators will be necessary to protect employees from exposure to AN. This aspect was recognized in the preamble to the proposal.

OSHA has concluded that if the permissible exposure limit is exceeded, employees must use respirators. This is necessary in order to provide the maximum amount of protection available in situations where engineering controls and work practices do not succeed in reducing exposures below permissible levels.

The affected employers have indicated that they have endeavored to determine, under the ETS, those job positions for which respirator use will be necessary for a large part of the workshift, under a 2 ppm standard. This achievement places the employers in a position to develop a detailed respirator program directed primarily at these employees. Items which might be considered for such a detailed program include making available a greater variety of respirators from which employees can choose, having a technician fully trained in respirator use and selection, and organizing the work so that part of the day can be spent in clean rooms or control rooms where the exposure limits are not exceeded. The nature of the work in many monomer and polymer manufacturing facilities, much of which is highly automated, lends itself to this type of program. The employer should also investigate the possibility for respirators with microphones, should communication on the job prove to be a problem.

Respiratory protection also has a role during maintenance operations as well as during emergency situations. We realize that respirators may be

needed in these types of operations, even over the long run. The standard is designed to control AN workplace emissions at the source, and, thus, to minimize the need for general use of respirators by employees.

In the proposal, OSHA included a proposed table of respirators for use with AN. The primary basis for the selection and evaluation of respirators in this table (Table I) was the NIOSH-OSHA respirator decision logic. The protection factors supplied in the table were based on qualitative fit testing, which involves only the facepiece-to-face seal. (Ex. 19). In addition to the Table, several other requirements for respirator usage were included in the proposal, concerning approval of respirators, replacement of cartridges and/or canisters, and cleaning of respirators.

A number of changes have been made from the proposed provisions, based primarily upon the recommendations of Darell Bevis, an acknowledged expert in the field of respiratory protection. These changes will be discussed below.

The proposal specified that where air-purifying respirators were to be used, they would have to be approved by NIOSH specifically for use with AN. NIOSH has since informed OSHA that they will not grant such approval because of AN's poor warning qualities. Since AN cannot be detected by odor until concentrations reach the 13-19 ppm range, it is not possible for the respirator wearer to detect leakage or breakthrough within the facepiece until he is clearly overexposed. Under the respirator decision logic, the use of air-purifying respirators should not be permitted for AN, because of this factor. However, OSHA has determined that air-purifying respirators, when used in a rigidly controlled program of proper fitting and frequent sorbent replacement, should be permitted for protection against low concentrations of AN, as prescribed in Table I of the standard. When the protection factors in the respirator table are followed, organic vapor cartridges and canisters can provide protection for employees.

Therefore, OSHA has revised its proposal to permit organic vapor cartridges and canisters to be used for AN. These sorbent containers must be approved by NIOSH for use with organic vapors. We must not however, that there are numerous factors which affect the performance of air-purifying respirators, including the sorbent material itself and the fit of the facepiece on the wearer. Other important factors include wearer acceptance and training.

Proper fit of the respirator is critical. A negative pressure is created within the facepiece when the wearer breathes. This may result in workplace air entering the facepiece through gaps and leaks in the facepiece seal, instead of passing through the sorbent material. Obtaining a proper fit on each employee may require the employer to provide two or three different mask styles.

The employee must be properly trained to wear the respirator, to know why the respirator is needed, and to understand the limitations of the respirator. An understanding of the hazard involved is necessary to enable the employee to take steps for his or her own protection. The respiratory protection program implemented by the employer must conform to that set forth in 29 CFR 1910.134. This provision contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

Under § 1910.134, the employer must check to see that the employees' respirators fit properly and that leakage is at a minimum. A rapid simple fit test can be performed at the start of each shift by each employee wearing a negative-pressure respirator. This test can be either a positive pressure test, in which the exhalation valve is closed and in which the wearer exhales into the facepiece to produce a positive pressure, or a negative pressure test, in which the inlet is closed and the wearer inhales so that the facepiece collapses slightly. Employees must be trained to perform this test.

The standard requires a qualitative fittest at the time of initial fitting and semiannually thereafter. Isoamyl acetate can be used to qualitatively test facepiece fit. If the employee can smell the isoamyl acetate while wearing the respirator, it can be concluded that the particular respirator will not provide suitable protection for that employee.

The proposal contained no specific requirement for periodic fit testing. However, as noted below, the issue was raised by OSHA in the proposal as to whether the more sophisticated quantitative fit test should be generally required. We have concluded that the periodic qualitative fit test can serve as a preliminary screening for all respirator users, to determine whether an employee's face-to-face piece seal is sufficient to permit the use of respirators designated in Table 1.

The standard also requires that each employer with 10 or more employees who must wear negative pressure respirators must provide quantitative fit testing for those employees at the time of initial fitting and semiannually thereafter. In a quantitative fit test, the level of leakage and degree of protection are specifically measured by sensitive instruments. These tests are more accurate and provide greater assurance that the respirator is providing proper protection to the employee. Whereas the qualitative fit test is subjective, relying upon the employee's sense of smell, the quantitative fit test uses instrumentation inside the facepiece to determine the integrity of the seal. One type of quantitative fit test involves using a simple hood, sodium chloride vapor, and automated instrumentation. At least one such device is commercially available at less than $10,000. These tests can be performed rapidly (10 to 20 minutes) and are relatively easy to perform. Since the standard will apply almost exclusively to monomer and polymer producers, it is reasonable to assume that these large companies can obtain the equipment for such testing.

OSHA requested views, arguments, and other comments on the issue of quantitative fit testing in the course of this rulemaking proceeding. The use of such testing has been endorsed by the Z88.2 subcommittee of ANSI as noted by Bevis in his testimony (Ex. 19). The equipment has been developed which makes quantitiative fit testing relatively easy to carry out, and it is universally recognized that it provides greater assurance of proper protection. We believe, therefore, that it is appropriate for employers with significant numbers of employees wearing negative pressure on respirators to be required to provide quantitative fit testing for those employees.

Under the ETS, employers were required to implement any practicable combination of engineering, work practices, and respiratory protective devices to lower their employees' AN exposures below a 2 ppm TWA. Much of the compliance activity under the ETS involved the implementation of respiratory protection programs. Therefore, there should be no need for a "transition period" for the implementation of respirator programs under the final standard. The standard requires that the employees exposed above the PEL as of the effective date of the standard must be provided with and must wear appropriate respirators in accordance with the selection criteria in Table I.

The proposal provided for the replacement of "filters" if an employee reported breathing resistance. This provision has been deleted from the final standard. As was noted at the hearing, organic vapor cartridges do not use "filters," which are generally used for protection against particulate hazards (Ex. 19). The vapor hazard associated with AN in the workplace should not present any breathing resistance difficulties, since there is no problem of clogged filters in this situation. Therefore, the requirement is not appropriate for a regulation on AN exposure.

Perhaps the most controversial element of the proposed respirator section involved the frequency of replacement of cartridges or canisters. It was contended by many in industry that the daily replacement of cartridges or canisters was wasteful, particularly if they were only used briefly during the workshift. A system of labeling of cartridges, it was argued, would assure that cartridges and canisters were replaced before the expiration of their service life (Ex. 92). OSHA does not agree with these contentions. As noted earlier, the very use of organic vapor cartridges and canisters for AN, which does not have good warning properties, runs totally counter to the respirator decision logic and to good industrial hygiene practice. However, OSHA has determined that it is necessary to allow their use under a limited set of circumstances, provided that that use is very narrowly restricted. The lack of end-of-service-life indicators for organic vapor cartridges used with AN masks it is necessary for OSHA to require the replacement of the sorbent at the completion of each shift (Ex. 11:(16)).

It should be noted, in addition, that even changing the sorbent container each shift may not assure protection. Testing data submitted by a respirator manufacturer and by NIOSH indicate that some organic vapor cartridges used for AN may not last for 8 hours, and that they may last for only 4 hours under humid conditions (Ex. 11:(12L); 11:(13L); 11:(14L)). This finding is particularly important in the context of this standard, since there are numerous monomer and polymer production facilities which operate under conditions of high humidity. It is clear that where the service life of a cartridge or canister is less than 8 hours, that cartridge or canister may have to be replaced again at some time during the workshift. The standard allows for such a situation by requiring the employer to replace cartridges or canisters before the end of their service life or at the completion of each shift, whichever comes first. The employer has the obligation to ascertain the service life of the cartridges and canisters to be used in his workplace, in order to assure that they are replaced as required by the standard.

On the issue of frequency of replacement of the cartridges Bevis stated:

> I am in full support of the change of the cartridge after each shift has ended, whether it has been used for 15 minutes or * * * 8 hours, since it is virtually impossible to assure how much air has been drawn through that cartridge or canister or to determine the specific minutes or hours of life. The activated charcoal sorbents in the organic vapor cartridges will sorb not only organic vapors but also moisture, shortening their service life (Ex. 19).

On questioning, he elaborated on the practice of labeling used cartridges as an alternative to replacement each shift:

> It's my firm opinion that when using sorbent-type cartridges and canisters (,) the most conservative approach must be taken * * * I never recommend—in fact, I'm a crusader against—reuse of sorbent type cartridges and canisters because I don't feel that they can safely be reused (Tr. 191).

We agree that in the limited use of the sorbent-type air purifying respirators, the most conservative approach must be taken in order to assure the most protection from that device.

As noted in the proposal, the wearing of a respirator can result in facial irritation at the face seal surface. To prevent this irritation and to minimize the discomfort of respirator use, the proposal would have permitted employees to periodically "wash" their faces and respirator facepieces. This provision has been modified in the final standard. It was noted at the hearing that an employee who "washed" his respirator facepiece might also wet the sorbent cartridge or canister, possibly rendering it ineffective or less effective. The employee's role, it was argued, was to make sure that he wore the facepiece properly (Tr. 193-4). We believe that the standard should reflect these concerns. The provision in the final standard has, therefore, been clarified to allow washing of the face, but only a wiping of the facepiece-to-face seal of the respirator itself. Cleaning of the active elements of the respirator should be in the hands of a trained person as part of a respirator program.

OSHA believes that if an employee receives training as to the purpose of his respirator and the proper method of wearing it, he will be less likely to do anything which will limit the protectiveness of the respirator program.

Emergency situations: Paragraph (i). The emergency provisions are substantially unchanged from those of the proposal. However, the revised definition of the term "emergency" limits the types and number of situations for which a written plan will be required. OSHA has determined that not all instances of release of AN above the ceiling limit should be viewed as emergencies. Only the "massive release" of AN is termed an emergency under the final standard.

It should be noted that the standard still requires the installation of an alarm system, to be activated by releases of AN above the ceiling. Although not an "emergency" per se as defined in the standard, the exceeding of the ceiling limit does necessitate the taking of protective action to assure that employees are not overexposed.

The alarm system will, in most cases, involve the installation of a continuous monitoring system which will detect AN concentrations at the ceiling limits to activate the alarm. Such monitoring systems have already been installed by some companies and are being used for generating area monitoring data in addition to detecting ceiling concentrations of AN (Exs. 11:(10); 87).

The need for an alarm system has been recognized by many of the affected companies (Exs. 11:(10); 11:(14); 11:(27)).

Protective clothing and equipment: Paragraph (j). The standard requires the employer to provide and assure that employees use protective clothing and equipment wherever there is potential for exposure to liquid AN. This provision is considerably narrower in scope than that in the proposal. It reflects the determination that solid PAN and other finished polymers do not represent significant sources of AN exposure. The new provisions require appropriate protective clothing and equipment only for "liquid AN," as defined in the standard, including polymer intermediates produced during the polymerization process.

The protective clothing provisions of the proposal elicited much comment and testimony from interested persons. The detailed requirements for providing, maintaining, and replacing protective clothing and equipment were criticized as not being sufficiently performance-oriented. Some comments noted that impermeable clothing was provided to the employee to protect him from skin contact with AN. Thus, when such AN-impermeable clothing became wet with AN, there was no need for the employee to remove the clothing immediately, as the proposal would have required, because there would be no skin exposure. Dow Badische recommended that the standard provide separate requirements for the handling of impermeable clothing, such as rubber gloves and suits, as opposed to coveralls and other permeable clothing (Ex. 149).

We have determined that these suggestions have merit, and the final standard incorporates appropriate changes. Where it is likely that impermeable clothing has contacted liquid AN such clothing must be washed down with water before being removed by the employee. The employee may then remove the clothing in the change room and proceed to shower. The clothing must then be placed in a regulated area and decontaminated.

A more complicated situation arises if an employee wearing AN-permeable clothing becomes wet with liquid AN. Understandably, this should only occur in accidental spills and emergencies. In this situation, the employee

shall remove the wetted clothing and shower immediately. The clothing shall then be placed in a regulated area and decontaminated in the same manner as impermeable clothing.

Clothing and equipment worn for protection from liquid AN must, of necessity, be impermeable to AN. The proposal would have required replacement of such clothing on at least a weekly basis. We have noted, however, that the actual need to provide replacement varies greatly with the conditions of use. We believe that the employer should be required to replace protective clothing and equipment as necessary to assure its protectiveness. Whereas this does not specify a given interval, it does require frequent inspection of clothing to make sure that it remains impermeable.

The washing down of impermeable suits, gloves, and the like before removal is intended to minimize the potential of skin contact with AN. The washdown should be sufficient to assure that the clothing will not release AN. The employee shall, nonetheless, shower at the end of the workshift.

The provision for decontamination of wetted protective clothing and equipment helps to resolve a major area of difficulty surrounding both the ETS and the proposal. The proposal required protective clothing to be placed in a closed container after use. This presented a problem of possible skin contact with and inhalation exposure to AN by persons opening these containers, as well as by persons who had to handle the clothing for disposal or laundering. In addition, the closing of the containers posed a potential for fire or explosion due to the volatility of the AN within the containers. The final standard deals with these problems by ventilating and washing down the contaminated clothing and equipment to remove their potential to release AN above 1 ppm.

Many maintenance operations, particularly those involving reactor cleaning, involve the potential of skin contact with liquid AN. The impermeable clothing requirements, along with respiratory protection requirements, are essential to the protection of employees engaged in these operations.

Housekeeping and waste disposal: Paragraphs (k) and (l). The proposal contained detailed housekeeping requirements for AN and PAN. As noted above, the final standard removes all references to PAN, since the new definition of "liquid AN" will cover any polymers and polymer intermediates deemed to carry a significant skin exposure potential.

Paragraph (k)(1) of the proposal required the employer to maintain work surfaces free of "accumulations" of AN and PAN. This paragraph has been sharply criticized as redundant with the permissible exposure limits, since the presence of even small amounts of liquid AN on a work surface would result in exposures above the PEL (Exs. 148; 11:(13)). Other parties contended that the term "accumulations" needed to be defined more precisely. The use of wipe tests and bulk liquid samples, it was argued, could lead to citations for the detection of "accumulations" of "nanogram quantities" of AN (Ex. 160).

Other provisions of the housekeeping section were found by some parties to be unnecessary and not in accordance with OSHA's intention to use performance language wherever practicable (Ex. 148). Vistron determined that the housekeeping section restricted the use of water flushing to wash down work surfaces. Such washing would take advantage of the solubility of AN in water, as well as its capacity for biodegradation by bacteria (Exs. 92; 146).

In light of these comments, and in order to provide a more performance oriented standard, OSHA has determined that there is no need for a detailed housekeeping section in the final AN standard. Where there may be skin or eye contact with liquid AN, the employer is already required to provide impermeable protective clothing and equipment to his employees. The detailed requirements as proposed would appear to add little, if any, protection to that provided by the permissible exposure limits. They would also have limited the use of water washdowns of work surfaces, which the final standard expressly requires in certain circumstances, as a means of controlling the potential for AN exposures. Recommended housekeeping activities are contained in appendixes A & B.

The final standard requires the employer to assure that surfaces are maintained free of visible accumulations of liquid AN. In addition, the employer must decontaminate (as defined in paragraph (b)) areas where spills are detected.

The housekeeping provisions have also been revised from the proposal to include a lead detection program for operations involving liquid AN. OSHA has determined that it is appropriate to require direct action by the employer to detect leaks and spills of liquid AN which may result in employee exposure. The details and frequency of such a program are not specified in the standard, because of the wide variation of workplace conditions and AN sources among the affected employers. However, the housekeeping provisions specify that the employer must decontaminate those areas in which leaks and spills are found. OSHA anticipates that the use of real-time continuous monitoring systems and portable detection units will be used both for detecting sources of AN and for determining whether an area has been decontaminated.

The proposal required that AN and PAN waste materials be placed in a closed container, labeled, and disposed of. The employer was required to inform those persons handling the materials of the AN content and the hazards of exposure to AN. These provisions drew strong comment from interested parties. It was contended that the enclosure of these materials constituted a fire and explosion hazard, since AN might be concentrated within the containers. It was also argued that the downstream handler of the materials would face a serious exposure potential when the container was opened (Ex. 149).

The record clearly reflects that the provisions in the proposal which dealt with waste disposal are not supported by the record and are inappropriate for the proper handling of AN. Therefore, these provisions have been revised accordingly. Waste materials containing or contaminated with liquid AN are to be placed in a regulated area. The materials may then be treated in one of two ways: They may either be placed under ventilation, or washed with water into the plant's process waste water system. When the materials no longer release AN in airborne concentrations above the action level, they may then be disposed of in the normal manner (clearly, if the material is incapable of releasing AN above the action level, there would be no need for the employer to carry out this washing or ventilation step on that material). The purpose of this new provision is threefold: First, it reduces the number of employees with potential for exposure to AN; second, it provides a means of dispensing with the detailed disposal and labeling requirements contained in the proposal; and, third, it provides a way for the employer to assure that the material will not expose downstream handlers.

As with protective clothing, many waste materials will not release AN above 1 ppm, even without the types of treatment provided for in paragraph (1). It is clear that the standard does not require such treatment in this case.

The discussion of the revised exemption provisions of the standard makes clear that solid polymeric materials are not considered to be a significant source of AN exposure. Therefore, the disposal of PAN scrap or debris, other than for those materials defined under "liquid AN," does not require the special treatment prescribed under paragraph (1). The deletion of the term "PAN" has been made in this paragraph, accordingly.

Hygiene facilities and practices: Paragraph (m). The proposal referenced § 1910.141 and its existing requirements for hygiene facilities and practices in all workplaces. In addition, the change room and shower facility provisions, § 1910.141 (e) and (d)(3), respectively, were specifically incorporated into the standard. OSHA believes that these provisions are particularly important where there is potential for contact with liquid AN, and where protective equipment and clothing may be required.

The proposed shower provisions would have required all employees "exposed to liquid AN and PAN" to shower at the end of the work shift. This requirement has drawn considerable comment from affected employers. The term "exposure" caused considerable confusion, since it was unclear what constituted exposure to AN in these circumstances (Ex. 149). It was suggested that the term be changed to "contact or suspected contact." In addition, it was argued that skin contact with PAN did not constitute a significant risk of AN exposure (Exs. 11:(I4); 148).

Several parties contended that the requirement for a shower at the end of a shift would not provide sufficient protection for an employee who has had skin contact with liquid AN. Such employee should be required to shower immediately after such contact, it was argued, because of the rapid absorption of AN through the skin (Exs. 11:(14); 149).

OSHA has determined that the shower provisions should be revised to reflect the comments and data received. The term "PAN", as has been noted elsewhere, is being deleted from this and other provisions of the standard. The list included in the definition of "liquid AN" includes those materials containing or made from AN which would be most likely to present a significant risk of skin exposure to AN.

The final standard contains a requirement for employees who have had or are suspected of having had skin contact with liquid AN to shower immediately after the contact is discovered. In addition, employees required to wear protective clothing to prevent skin contact with liquid AN are required to shower at the end of the shift. These requirements recognize the nature of the skin exposure hazard, and effectively limit the need for showers to those employees who may have contacted liquid AN.

The lunchroom provisions of the proposal have also come under close scrutiny. OSHA has determined that lunchroom provisions are not required in the final standard for several reasons. First, because the airborne hazard involves vapor rather than particulate, there is not a need for a filtered, positive pressure air supply in lunchrooms (Ex. 156). Second, the standard already prohibits eating, drinking, and smoking in regulated areas. Employees are not permitted to have food, beverages, or smoking products in areas above the permissible exposure limits. Third, the final standard retains the requirement for employees exposed above the TWA to wash before eating. Airborne concentrations above the PEL imply the concurrent possibility of skin contact with AN. Even though the standard contains a separate requirement for employees who contact liquid AN to shower afterwards, OSHA believes that this additional precautionary measure is appropriate in light of the nature of the AN exposure hazard.

Medical surveillance: Paragraph (n). The final standard, like the ETS and the Proposal, requires that each employer institute a medical surveillance program for all employees who are or will be exposed to AN at or above the action level. OSHA finds that a medical surveillance program is both necessary and appropriate to most effectively determine whether the health of employees exposed to AN is adversely affected by such exposure, and to develop information on occupational illnesses. The authority to include such a provision in this standard is set forth in section 6(b)(7) of the Act.

The standard requires that the medical surveillance program provide each covered employee with an opportunity for medical examination. All examinations and procedures are required to be performed by or under the supervision of a licensed physician, and provided without cost to the employee. While the physician will usually be selected by the employer, the standard does not so mandate, leaving the employer free to institute alternative procedures such as joint selection with employee or selection by the employee. Clearly a medical examination is most appropriately conducted by a licensed physician. However, certain parts of the required medical surveillance program do not necessarily require a physician's specific expertise and may be conducted by another person under the supervision of the physician (Ex. 141). As mandated by section 6(b)(7) of the Act, the medical examinations and procedures required by OSHA standards must be provided at no cost to the employee.

The standard requires that the medical examination include a work history, a medical history and a physical examination of the affected employees. The content of the examination is based upon recommendations from NIOSH (Exs. 42; 41) and upon procedures presently followed by several companies in their clinical evaluation of employees exposed to acrylonitrile (Exs. 128; 149). The purpose of these requirements is to make an initial medical assessment of each employee and to establish a baseline health condition against which future changes in an employee's health may be compared.

The medical surveillance provisions of the standard contain specific testing requirements, with concentration on the peripheral and central nervous systems, respiratory system and gastrointestinal system. Based upon the data from the du Pont and MCA studies of exposure to AN, these vital sites must be considered to be possible target sites for AN-induced cancer.

However, due to the lack of site-specificity associated with AN-induced cancer, all systems must be examined thoroughly (Exs. 42; 89; 92; 160). OSHA believes that these provisions will enable the examining physician to detect and hopefully make possible early treatment for any cancers which may develop due to past exposures to AN.

The standard requires fecal occult blood testing for workers over 40 years of age. This is a nontraumatic, noninvasive procedure for the early detection of gastrointestinal disease which is available and commonly used medically as a screening technique. OSHA has therefore deleted the provision requiring the routine proctosigmoidoscopic examination of workers exposed to AN. However, should the results of the fecal occult blood testing (as well as other medical tests or examination) indicate that, in the judgment of the examining physician, further testing is necessary, such additional testing would then be performed (cf. Exs. 14:(37); 42; TR. 704; 708; 710).

The standard requires that the employer provide the physician with certain information. This includes the following: (1) A copy of the regulation; (2) a description of the affected employee's duties as they relate to the employee's exposure; (3) the results of the employee's exposure monitoring; (4) the employee's anticipated exposure level; (5) whether any personal protective equipment has been or will be used; and (6) information from previous medical examinations of the affected employee which is not otherwise readily available to the physician. The purpose of making this information available to the physician is to aid in the evaluation of the employee's health in relation to his assigned duties and fitness to wear personal protective equipment when required.

The employer is required to obtain a written opinion from the examining physician containing the following information: (1) The results of the medical tests performed; (2) the physician's opinion as to whether the employee has any detected medical conditions

which would place the employee at increased risk of material impairment of health from exposure to AN; (3) any recommended limitations upon the employee's exposure to AN or upon the use of protective clothing and equipment, such as respirators; and (4) a statement that the employee has been informed by the physician of the test results of the medical examination and of any medical conditions which require further examination or treatment. This written opinion must not reveal specific findings or diagnoses which are unrelated to occupational exposure. A copy of the written opinion must be provided to the affected employee by the employer.

Commentors have objected to the requirements for the physician's written opinion as unnecessary and burdensome (Exs. 11: (25) Ex. 148; 160). They believe the requirements should be limited to situations where the findings are adverse (Exs. 73; 153).

These views are unacceptable to OSHA. Since the employer has the ultimate responsibility to assure the protection of the worker's health, where the worker's health has not been adversely affected, transmittal of the doctor's opinion serves to inform both patient and employer and provides documentary evidence that the prescribed tests were performed and evaluated. The requirement that the employee be provided with a copy of the physician's written opinion will assure that the employee is informed of the results of the medical examination and may take any necessary or appropriate action. This is consistent with those provisions of the Act which establish and implement the employee's right to know about occupational hazards and their effects. The purpose of requiring that specific findings or diagnoses unrelated to occupational exposure not be included in the written opinion is to encourage employees to submit to medical examination by removing the fear that employers may find out information about their physical condition that has no relation to their occupational exposures.

It has been suggested that physical examinations are not necessary for people under 40 and in good health (Ex. 160). This is contrary to the intent of medical surveillance. Workers under 40 may already have been exposed to AN for 15 to 20 years. Since the carcinogenic response may vary widely depending to a great extent on individual susceptibilities the long latency periods associated with carcinogens may also vary greatly among those exposed to cancer-causing substances. In addition medical surveillance is intended to aid in the early detection of cancer and other chronic effects so as to facilitate treatment of these conditions.

It has been suggested that provision be made for medical surveillance to include those employees who have a history of AN exposure but are no longer actively working with AN (Ex. 11:(2)). No such provision has been included in the standard, as OSHA has determined that the inclusion of past em; ployees in a medical surveillance program would be unnecessarily burdensome and administratively infeasible. It would be extremely difficult, if not impossible, to determine which employees may have been exposed to AN and for how long, and to locate many such employees so as to inform them of the medical surveillance program. In addition, where the employee has worked for more than one employer, it would be difficult to determine which employer should bear the cost of such medical surveillance.

Medical removal protection. Medical removal protection was raised as an issue in the AN proposal. This requirement would maintain the rate of pay, seniority and other rights of an employee who is transferred or removed from his job to protect him from material impairment of health, as a result of an increased health risk from exposure to AN.

OSHA's primary goal is to assure that no employee suffers material impairment of health or functional capacity. The Agency does not favor transfer or removal as an alternative to controlling the level of a toxic substance in the workplace environment. Moreover, once full compliance with the permissible exposure limits is achieved by engineering controls and work practices, the need to transfer or remove employees from exposure to AN should arise infrequently.

Limited evidence on this issue was received during this proceeding. OSHA has conducted extensive hearings on medical removal protection in connection with the development of a standard for occupational exposure to lead. The final lead standard, including resolution of the question of medical removal protection, is expected to issue shortly. Once the lead standard is issued, OSHA will consider the extent to which the conclusions reached therein on medical removal protection are appropriate for acrylonitrile, and will propose the inclusion of any appropriate provisions in the AN standard.

Employee information and training: Paragraph (o). The standard requires the employer to provide a training program for employees exposed to AN. OSHA believes that an information and training program is essential for the protection of employees, because an employee can do much to protect himself if aware of the nature of the hazards in the workplace. To be effective, an employee education system must, at the minimum, apprise the employee of the specific hazards associated with his or her work environment. For this reason, the employer is required to inform each employee exposed to AN of the nature of the related health problems, the necessity for exposure control, and the medical and industrial hygiene programs. Such an educational program will go far in assuring that employees know the facts about AN and its proper handling.

The content of the training program is intended to apprise the employees of several factors: (1) The hazards to which they are exposed; (2) the action they can take to protect themselves, including avoiding exposure, using respiratory protection and taking medical examinations; (3) their role in reducing exposures; and (4) the contents of this standard. Section 6(b)(7) of the Act makes it clear that these are appropriate goals of an employee training program, and the standard, therefore, includes such provisions.

The employer is also required to provide, upon request, all materials relating to the training program to the Assistant Secretary and the Director. This is intended to provide an objective check of compliance with the requirements of the standard.

OSHA recognizes that AN may be one of many chemicals to which an employee may be exposed simultaneously in the workplace. The education and training requirements in this standard contain those elements which OSHA believes to be basic. The format of the training and information program is not rigid. An employer may, if he chooses, incorporate the required information for AN into a total program of training and education which is to be provided to his employees (Ex. 11:(14)).

Signs and labels: Paragraph (p). The requirement of the standard regarding the posting of warning signs and affixing caution labels remains primarily the same as that in the proposal. The broadening of the exemption provisions of the standard will result in a minimum of products and materials which will be required to be labeled. In addition, the wording of the signs for regulated areas has been slightly changed. These requirements are consistent with section 6(b)(7) of the Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed.

Signs. The standard requires the posting of warning signs in regulated areas. These signs are intended to supplement the training which employees are required to receive under the standard. Even trained employees will need to be reminded of the locations of regulated areas and the dangers of entering those areas. In addition,

other workers, such as employees of independent maintenance contractors who are authorized to enter particular regulated areas, need to be warned of the hazard and reminded to use protective equipment. OSHA believes that both signs and training are necessary to adequately apprise employees of the hazards of acrylonitrile exposure.

The standard specifies the wording of the warning signs for regulated areas, in order to assure that the proper warning is given to employees. Some participants in the rulemaking have suggested that the word "Cancer" on the signs be replaced by "Cancer-Suspect Agent", or "Toxic Substance" (Exs. 146; 149). OSHA does not believe that the use of the term "Cancer Hazard" overstates the hazard. The reference to cancer provides the necessary warning as to the hazard associated with exposure to acrylonitrile.

It has been further suggested that the word "Danger" be replaced by the word "Caution". OSHA feels that the word "Danger" is appropriate in light of the evidence of carcinogenicity of acrylonitrile. Furthermore, the word "Danger" is used to attract the attention of workers, to alert them to the fact that they are in a hazardous area, i.e., an area where the permissible exposure limit is exceeded, and to emphasize the importance of the message to follow. The use of the word "Danger" is consistent with recent OSHA health standards dealing with carcinogens.

The signs have been changed from the proposal to read "Respirators May Be Required," instead of "Respirators Required." The reason for this involves the difference between the air concentrations in the regulated area and an employee's TWA exposure. There are many areas in which AN concentrations exceed 2 ppm, but where the employee's TWA exposures will not exceed the permissible limits. Such an employee would not be required to wear a respirator, even though the proposed sign would have indicated otherwise. The final standard has been revised to provide a more appropriate warning to employees entering the regulated area.

Labels. The standard requires the use of warning lablels on all containers of liquid AN and materials made from and/or containing AN which are not exempted from the standard under paragraph (a)(2). This requirement imposes upon the employer the obligation to assure that all such containers within his workplace are at all times properly labeled, in order that his employees be apprised of the hazard.

The revision of the exemption provisions in the final standard will greatly relieve the burden of labeling of materials made from and/or containing AN. Only those materials which pose a significant potential for exposing employees to AN are required to be labled under the standard.

The standard requires that the labels remain affixed when the AN and AN-based materials leave the employer's workplace. Some comments questioned OSHA's jurisdiction to impose such a requirement (Exs. 156; 11:(14); 146). The purpose of this requirement is to assure that all employees, not only those of a particular employer, are apprised of the hazardous nature of acrylonitrile exposure. It is OSHA's view that informing employees of the hazards to which they are exposed is an important element in reducing occupational disease and injury, and one of the significant purposes of the Occupational Safety and Health Act. Section 6(b)(7) of the Act, which explicitly provides for regulations which require the use of labels or other appropriate forms of warning, is broadly drawn. This section does not limit the employer's obligation of informing employees of hazardous conditions to the employer's own employees. When an employer manufacturers, formulates, or sells a product containing a toxic substance, that employer is exposing not only his own employees, but also the employees of other employers involved in handling, transporting, or using the product. The extent of the obligation to inform should be commensurate with the extent of the exposure. This is especially true where the manufacturer, formulater, or seller will, in many cases, be the only employer capable, through his knowledge of the product, of providing the information necessary for protection of employees. A narrower reading of the statutory authority would defeat the protective purposes of the Act by effectively preventing the downstream employee from obtaining adequate information as to the hazard. Furthermore, the use of the labels required by the standard will alert other employers who utilize or handle the product and who would not otherwise know of the presence of acrylonitrile in their workplace, of their obligation to comply with the standard. OSHA, therefore, feels that this requirement is necessary and appropriate to effectuate the purposes of the Act.

The standard prescribes the legend that must be included on the label. This is to assure that employees are alerted to the fact they they are handling acrylonitrile and to the hazards involved.

The issue of labeling was of great concern as proposed, because the number of products which potentially might have required lablels was substantial. The listing of exempted polymer products in paragraph (a)(2)(i) of the final standard makes it clear that these specific products do not have to be labeled. Other than liquid AN itself, OSHA does not anticipate that many products containing and/or made for AN will require labeling under the final standard. This reflects the recognition that most AN-based materials in downstream workplaces do not have a significant potential to expose employees to AN during processing use, and handling.

Recordkeeping: Paragraph (q). Section 8(c)(3) of the Act provides for the promulgation of regulations requiring employers to maintain accurate records of employee exposures to potentially toxic or harmful physical agents which are required to be monitored or measured.

The standard provides that records must be kept to identify the employee and to accurately reflect the employee's exposure. Specifically, it must include the following information: (a) The names, social security numbers, and job classifications of the employees monitored; (b) the dates, number, duration, and results of each of the samples taken, including a description of the representative sampling procedure and equipment used to determine employee exposure where applicable; (c) the type of respiratory protective devices if any, worn by the employee; and (d) a description of the sampling and analytical methods used, and evidence of their accuracy.

The standard also requires that the employer keep an accurate medical record for each employee who is subject to medical surveillance. Section 8(c) of the Act authorizes the promulgation of regulations requiring any employer to keep such records regarding the employer's activities relating to the Act as are necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational illnesses. OSHA believes that medical records (like exposure monitoring records) are necessary and appropriate to both the enforcement of the standard and the development of information regarding the causes and prevention of illness.

As explained above, it is necessary to relate employees' medical conditions with their exposures in order to develop information regarding cause and prevention. Medical records are necessary and appropriate for this purpose. In addition, medical records are necessary for the proper evaluation of an employee's health. For all of these reasons, medical records have been required in the final standard.

The standard requires that employees or their designated representatives be provided access to examine and copy records of required monitoring. The purpose of this provision is to

assure employees that their exposure is being properly monitored and that they are working in a safe and healthful environment. Section 8(c)(3) of the Act explicitly provides "employees or their representatives with an opportunity to observe * * * and to have access to the records thereof."

The final standard requires that employee medical records be made available upon request for examination and copying by the affected employee or former employee, or a physician designated by the affected employee or former employee. The purpose of this provision is to protect the employee's health by authorizing his designated physician to have access to medical records which may be useful in the diagnosis of illness.

The standard requires employers relying upon objective data for exemption under paragraph (a)(2)(ii) to maintain records of that data and of the basis for their reliance on that data. These records shall be maintained for the duration of the employer's reliance on that data for exemption.

Observation of monitoring: Paragraph (r). Section 8(c)(3) of the Act requires that employers provide employees and their representatives with the opportunity to observe monitoring of employee exposures to toxic substances or harmful physical agents. In accordance with this section, the standard contains provisions for such observation of monitoring of acrylonitrile exposures. To assure that the right to observe is meaningful, observers are entitled to receive an explanation of the measurement procedure, to observe all steps related to the measurement procedure, and to record the results obtained.

The observer, whether an employee or a designated representative, must be provided with, and is required to use, any personal protective equipment required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

Effective date: Paragraph (s). The effective date of the standard is November 2, 1978, thirty days from publication. OSHA has determined that the circumstances of this rulemaking make it unnecessary to allow a longer period of time. Under the ETS, employers were required to perform many of the activities, such as initial monitoring, respiratory protection, and engineering control plans, which are to be required under the final standard. Since the scope of the final standard is narrower than that of the ETS, it is anticipated that all employers covered by the final standard were also subject to the ETS. There should be, therefore, no need for delay in requiring these employers to implement the provisions of the standard. In addition, the standard permits monitoring results and medical examinations obtained under the ETS to serve as initial monitoring and initial medical surveillance under the final standard.

Employers are required to reduce employee exposures to the permissible exposure limits solely by means of feasible engineering controls and work practices within 2 years of the effective date of the standard, or November 2, 1980. The record reflects a wide range of present exposure situations and capabilities of engineering development. Some companies have reported that most of their opreations are already below 2 ppm (Exs. 11:(14); 11:(10); 2:(21)). One producer expects to have engineering controls in place shortly (Ex. 92). One major company has predicted that the completion schedule for engineering projects to reach 2 ppm may take 2 to 3 years (Ex. 11:(27)). Other companies which have developed plans for engineering controls to reach 2 ppm have indicated that they will need leadtime, but have not established any timetable for implementation (Tr. 1016-1017; 978).

An SPI witness estimated that project definition for engineering solutions to reach 2 ppm/10 ppm would take about 6 months, and that implementation of those solutions would take up to 24 additional months (Ex. 74).

OSHA has determined that a 2-year period for installation of engineering controls is reasonable for the AN industry as a whole. Although some employers will be able to complete implementation of controls well within the 2-year time frame, OSHA believes that certain sectors of the industry, primarily resin and elastomer manufacturing, may require the full 2 years to comply. While employers are not required to complete installation of engineering controls until November 2, 1980, they are required to develop a compliance program which provides for completion of controls by that date, and to follow the schedule set out in the program. Failure to develop an adequate program, or failure to implement the progressive steps set out in the program to achieve compliance by November 2, 1980, will subject the employer to citation.

Training programs are to be implemented within 60 days of the effective date of the standard. OSHA believes that this should provide sufficient lead time, particularly in light of the training requirements of the ETS.

Appendices

Four appendices have been included in this permanent standard. These appendices have been included primarily for purposes of information. None of the statements contained therein should be construed as establishing a mandatory requirement not otherwise imposed by the standards, or as detracting from an obligation which the standard does impose.

The information contained in appendices A and B is designed to aid the employer is complying with requirements of the standard. The information in appendix C primarily provides information needed by the physician to evaluate the results of the medical examination. It should be noted that paragraph (o) specifically requires that the information contained in appendices A and B be provided to employees as part of their information and training program.

A new appendix D has been added to the final standard. This appendix gives the details of NIOSH method S-156, together with the NIOSH and OSHA variations on that method, for use in monitoring employee exposures to acrylonitrile. Other methods of sampling and analysis are available in the record of the rulemaking, and may be obtained from the OSHA Docket Office.

The contents of the appendices have been revised to reflect changes from the proposal. In addition, efforts have been made to clarify those sections in the appendices as proposed which were either inconsistent or unclear in relation to the standard.

Authority

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, D.C. 20210.

Accordingly, pursuant to sections 4(b)(2), 6(b), 6(c), and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1592, 1593, 1596, 1599; 29 U.S.C. 653, 655, 657), the specific statutes referred to in section 4(b)(2), Secretary of Labor's Order No. 8-76 (41 FR 25059), and 29 CFR part 1911, part 1910 of title 29, Code of Federal Regulations, is hereby amended by deleting the emergency temporary standard for occupational exposure to acrylonitrile at § 1910.1045 and adding a new permanent standard for occupational exposure to acrylonitrile as § 1910.1045, and by deleting the reference to acrylonitrile from table Z-1 of § 1910.1000. In addition, pursuant to section 4(b)(2) of the act, OSHA has determined that this new standard in § 1910.1045 is more effective than the corresponding standards now in subpart B of part 1910, and in parts 1915, 1916, 1917, 1918, and 1926 of title 29, Code of Federal Regulations. Therefore, these corresponding standards are superseded by this new § 1910.1045. This determination, and the application of the new

standard to the maritime and construction industries, are implemented by revising paragraph (c) to § 1910.19.

In conjunction with the publication of the emergency temporary standard (43 FR 2586; Jan. 17, 1978), pursuant to sections 4(b)(2), 6(c), and 8(c) of the Act (84 Stat. 1592; 1996; 1599; 29 U.S.C. 653, 655, 657), title 29 of the Code of Federal Regulations was amended by adding a new paragraph (c) to § 1910.19, and by deleting the reference to acrylonitrile from table Z-1 of § 1910.1000. The authority for these amendments pursuant to section 6(c) of the act has expired. These amendments are to be carried forward in accordance with the promulgation of the new permanent standard, as noted above, pursuant to sections 4(b)(2), 6(b), 6(c), and 8(c) of the act (84 Stat. 1592, 1593, 1596, 1599; 29 U.S.C. 653, 655, 657).

Signed at Washington, D.C., this 22d day of September 1978. These amendments are effective on November 2, 1978

EULA BINGHAM,
Assistant Secretary of Labor.

Part 1910 of title 29 of the Code of Federal Regulations is hereby amended as follows:

1. Paragraph (c) of § 1910.19 is revised to read as follows:

§ 1910.19 Special provisions for air contaminants.

* * * * *

(c) *Acrylonitrile.* Section 1910.1045 shall apply to the exposure of every employee to acrylonitrile in every employment and place of employment covered by §§ 1910.12, 1910.13, 1910.14, 1910.15, or 1910.16, in lieu of any different standard on exposure to acrylonitrile which would otherwise be applicable by virtue of any of those sections.

§ 1910.1000 [Amended]

* * * * *

2. Section 1910.1000 is amended by deleting the line "Acrylonitrile——— 20———45" from table Z-1 of that section.

3. Section 1910.1045 is revised to read as follows:

§ 1910.1045 Acrylonitrile.

(a) *Scope and application.* (1) This section applies to all occupational exposures to acrylonitrile (AN), Chemical Abstracts Service Registry No. 000107131, except as provided in paragraphs (a)(2) and (a)(3) of this section.

(2) This section does not apply to exposures which result solely from the processing, use, and handling of the following materials:

(i) ABS resins, SAN resins, nitrile barrier resins, solid nitrile elastomers, and acrylic and modacrylic fibers, when these listed materials are in the form of finished polymers, and products fabricated from such finished polymers;

(ii) Materials made from and/or containing AN for which objective data is reasonably relied upon to demonstrate that the material is not capable of releasing AN in airborne concentrations in excess of 1 ppm as an eight (8)-hour time-weighted average, under the expected conditions of processing, use, and handling which will cause the greatest possible release; and

(iii) Solid materials made from and/or containing AN which will not be heated above 170° F during handling, use, or processing.

(3) An employer relying upon exemption under paragraph (a)(2)(ii) shall maintain records of the objective data supporting that exemption, and of the basis of the employer's reliance on the data, as provided in paragraph (q) of this section.

(b) *Definitions.* "Acrylonitrile" or "AN" means acrylonitrile monomer, chemical formula $CH_2=CHCN$.

"Action level" means a concentration of AN of 1 ppm as an eight (8)-hour time-weighted average.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

"Authorized person" means any person specifically authorized by the employer whose duties require the person to enter a regulated area, or any person entering such an area as a designated representative of employees for the purpose of exercising the opportunity to observe monitoring procedures under paragraph (r) of this section.

"Decontamination" means treatment of materials and surfaces by water washdown, ventilation, or other means, to assure that the materials will not expose employees to airborne concentrations of AN above 1 means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or designee.

"Emergency" means any occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment, which results in an unexpected massive release of AN.

"Liquid AN" means AN monomer in liquid form, and liquid or semiliquid polymer intermediates, including slurries, suspensions, emulsions, and solutions, produced during the polymerization of AN.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

(c) *Permissible exposure limits.* (1) *Inhalation.* (i) *Time weighted average limit (TWA).* The employer shall assure that no employee is exposed to an airborne concentration of acrylonitrile in excess of two (2) parts acrylonitrile per million parts of air (2 ppm) as an eight (8)-hour time-weighted average.

(ii) *Ceiling limit.* The employer shall assure that no employee is exposed to an airborne concentration of acrylonitrile in excess of ten (10) ppm as averaged over any fifteen (15)-minute period during the working day.

(2) *Dermal and eye exposure.* The employer shall assure that no employee is exposed to skin contact or eye contact with liquid AN.

(d) *Notification of regulated areas and emergencies.* (1) *Regulated areas.* Within thirty (30) days following the establishment of a regulated area pursuant to paragraph (f) of this section, the employer shall report the following information to the OSHA Area Office:

(i) The address and location of each establishment which has one or more regulated areas;

(ii) The locations, within the establishment, of each regulated area;

(iii) A brief description of each process or operation which results in employee exposure to AN in regulated areas; and

(iv) The number of employees engaged in each process or operation within each regulated area which results in exposure to AN, and an estimate of the frequency and degree of exposure that occurs.

Whenever there has been a significant change in the information required to be reported by this paragraph, the employer shall promptly provide the new information to the OSHA Area Office.

(2) *Emergencies.* Emergencies, and the facts obtainable at that time, shall be reported within seventy-two (72) hours of the initial occurrence to the OSHA Area Office. Upon request of the OSHA Area Office, the employer shall submit additional information in writing relevant to the nature and extent of employee exposures and measures taken to prevent future emergencies of a similar nature.

(e) *Exposure monitoring.*—(1) *General.* (i) Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to AN over an eight (8)-hour period.

(ii) For the purposes of this section, employee exposure is that exposure which would occur if the employee were not using a respirator.

(2) *Initial monitoring.* Each employer who has a place of employment in which AN is present shall monitor each such workplace and work operation to accurately determine the airborne concentrations of AN to which employees may be exposed.

(3) *Frequency.* (i) If the monitoring required by this section reveals employee exposure to be below the action level, the employer may discontinue monitoring for that employee.

(ii) If the monitoring required by this section reveals employee exposure to be at or above the action level but below the permissible exposure limits, the employer shall repeat such monitoring for each such employee at least quarterly. The employer shall continue these quarterly measurements until at least two consecutive measurements taken at least seven (7) days apart, are below the action level, and thereafter the employer may discontinue monitoring for that employee.

(iii) If the monitoring required by this section reveals employee exposure to be in excess of the permissible exposure limits, the employer shall repeat these determinations for each such employee at least monthly. The employer shall continue these monthly measurements until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limits, and thereafter the employer shall monitor at least quarterly.

(4) *Additional monitoring.* Whenever there has been a production, process, control, or personnel change which may result in new or additional exposures to AN, or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to AN, additional monitoring which complies with this paragraph shall be conducted.

(5) *Employee notification.* (i) Within five (5) working days after the receipt of the results of monitoring required by this paragraph, the employer shall notify each employee in writing of the results which represent that employee's exposure.

(ii) Whenever the results indicate that the representative employee exposure exceeds the permissible exposure limits, the employer shall include in the written notice a statement that the permissible exposure limits were exceeded and a description of the corrective action being taken to reduce exposure to or below the permissible exposure limits.

(6) *Accuracy of measurement.* The method of measurement of employee exposures shall be accurate, to a confidence level of 95 percent, to within plus or minus 35 percent for concentrations of AN at or above the permissible exposure limits, and plus or minus 50 percent for concentrations of AN below the permissible exposure limits.

(f) *Regulated areas.* (1) The employer shall establish regulated areas where AN concentrations are in excess of the permissible exposure limits.

(2) Regulated areas shall be demarcated and segregated from the rest of the workplace, in any manner that minimizes the number of persons who will be exposed to AN.

(3) Access to regulated areas shall be limited to authorized persons or to persons otherwise authorized by the act or regulations issued pursuant thereto.

(4) The employer shall assure that food or beverages are not present or consumed, tobacco products are not present or used, and cosmetics are not applied in the regulated area.

(g) *Methods of compliance.*—(1) *Engineering and work practice controls.* (i) By November 2, 1980, the employer shall institute engineering and work practice controls to reduce and maintain employee exposures to AN, to or below the permissible exposure limits, except to the extent that the employer establishes that such controls are not feasible.

(ii) Wherever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to or below the permissible exposure limits, the employer shall nonetheless use them to reduce exposures to the lowest levels achievable by these controls, and shall supplement them by the use of respiratory protection which complies with the requirements of paragraph (h) of this section.

(2) *Compliance program.* (i) The employer shall establish and implement a written program to reduce employee exposures to or below the permissible exposure limits solely by means of engineering and work practice controls, as required by paragraph (g)(1) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(A) A description of each operation or process resulting in employee exposure to AN above the permissible exposure limits;

(B) An outline of the nature of the engineering controls and work practices to be applied to the operation or process in question;

(C) A report of the technology considered in meeting the permissible exposure limits;

(D) A schedule for implementation of engineering and work practice controls for the operation or process, which shall project completion no later than November 2, 1980; and

(E) Other relevant information.

(iii) The employer shall complete the steps set forth in the compliance program by the dates in the schedule.

(iv) Written plans shall be submitted upon request to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, or any affected employee or representative.

(v) The plans required by this paragraph shall be revised and updated at least every six (6) months to reflect the current status of the program.

(h) *Respiratory protection.*—(1) *General.* The employer shall assure that respirators are used where required by this section to reduce employee exposure to within the permissible exposure limits. Respirators shall be used in the following circumstances:

(i) During the time period necessary to install or implement feasible engineering and work practice controls;

(ii) In work operations, such as maintenance and repair activities or reactor cleaning, in which the employer establishes that engineering and work practice controls are not feasible;

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the permissible exposure limits; and

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respiratory protection is required under this section, the employer shall select and provide, at no cost to the employee, the appropriate type of respirator from table I below, and shall assure that the employee wears the respirator provided.

TABLE I.—*Respiratory Protection for Acrylonitrile (AN)*

Concentration of AN or condition of use	Respirator type
(a) Less than or equal to 20 ppm	(1) Chemical cartridge respirator with organic vapor cartridge(s) and half-mask facepiece; or (2) Supplied air respirator with half-mask facepiece.
(b) Less than or equal to 100 ppm or maximum use concentration (MUC) of cartridges or canisters, whichever is lower.	(1) Full facepiece respirator with (A) organic vapor cartridges, (B) organic vapor gas mask chin-style, or (C) organic vapor gas mask canister, front- or back-mounted; (2) Supplied air respirator with full facepiece; or (3) Self-contained breathing apparatus with full facepiece.
(c) Less than or equal to 4,000 ppm	(1) Supplied air respirator operated in the positive pressure mode with full facepiece, helmet, suit, or hood.
(d) Greater than 4,000 ppm or unknown concentration.	(1) Supplied air and auxiliary self-contained breathing apparatus with full facepiece in positive pressure mode; or

TABLE I.—*Respiratory Protection for Acrylonitrile (AN)*

Concentration of AN or condition of use	Respirator type
	(2) Self-contained breathing apparatus with full facepiece in positive pressure mode.
(e) Firefighting	Self-contained breathing apparatus with full facepiece in positive pressure mode.
(f) Escape	(1) Any organic vapor respirator, or (2) Any self-contained breathing apparatus.

(ii) The employer shall select respirators from among those approved for use with organic vapors by the National Institute for Occupational Safety and Health under the provisions of 30 CFR part 11.

(3) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b), (d), (e), and (f).

(ii) Where air/purifying respirators (chemical cartridge- or canister-type) are used, the air-purifying canister or cartridge(s) shall be replaced prior to the expiration of their service life or at the completion of each shift, whichever occurs first. A label shall be attached to the cartridge or canister to indicate the date and time at which it is first installed on the respirator.

(iii) *Testing.* Fit testing of respirators shall be performed to assure that the respirator selected provides the protection required by table I.

(A) *Qualitative fit.* The employer shall perform qualitative fit tests at the time of initial fitting and at least semiannually thereafter for each employee wearing respirators.

(B) *Quantitative fit.* Each employer with more than 10 employees wearing negative pressure respirators shall perform quantitative fit testing at the time of initial fitting and at least semiannually thereafter for each such employee.

(iv) Employees who wear respirators shall be allowed to wash their faces and to wipe clean the face-to-facepiece seals on their respirators to minimize potential skin irritation associated with respirator use.

(i) *Emergency situations.*—(1) *Written plans.* (*i*) A written plan for emergency situations shall be developed for each workplace where liquid AN is present. Appropriate portions of the plan shall be implemented in the event of an emergency.

(*ii*) The plan shall specifically provide that employees engaged in correcting emergency conditions shall be equipped as required in paragraph (h) of this section until the emergency is abated.

(*iii*) Employees not engaged in correcting the emergency shall be evacuated from the area and shall not be permitted to return until the emergency is abated.

(2) *Alerting employees.* Where there is the possibility of employee exposure to AN in excess of the ceiling limit, a general alarm shall be installed and used to promptly alert employees of such occurrences.

(j) *Protective clothing and equipment.*—(1) *Provision and use.* Where eye or skin contact with liquid AN may occur, the employer shall provide at no cost to the employee, and assure that employees wear, impermeable protective clothing or other equipment to protect any area of the body which may come in contact with liquid AN. The provision of §§ 1910.132 and 1910.133 shall be complied with.

(2) *Cleaning and replacement.* (i) The employer shall clean, launder, maintain, or replace protective clothing and equipment required by this section as needed to maintain their effectiveness.

(ii) The employer shall assure that impermeable protective clothing which contacts or is likely to have contacted liquid AN shall be decontaminated before being removed by the employee.

(iii) The employer shall assure that an employee whose nonimpermeable clothing becomes wetted with liquid AN shall immediately remove that clothing and proceed to shower. The clothing shall be decontaminated before it is removed from the regulated area.

(iv) The employer shall assure that no employee removes protective clothing or equipment from the change room, except for those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(v) The employer shall inform any person who launders or cleans protective clothing or equipment of the potentially harmful effects of exposure to AN.

(k) *Housekeeping.* (1) All surfaces shall be maintained free of visible accumulations of liquid AN.

(2) For operations involving liquid AN, the employer shall institute a program for detecting leaks and spills of liquid AN, including regular visual inspections.

(3) Where spills of liquid AN are detected, the employer shall assure that surfaces contacted by the liquid AN are decontaminated. Employees not engaged in decontamination activities shall leave the area of the spill, and shall not be permitted in the area until decontamination is completed.

(k) *Waste disposal.* AN waste, scrap, debris, bags, containers, or equipment shall be decontaminated before being incorporated in the general waste disposal system.

(m) *Hygiene facilities and practices.* (1) Where employees are exposed to airborne concentrations of AN above the permissible exposure limits, or where employees are required to wear protective clothing or equipment pursuant to paragraph (j) of this section, the facilities required by 29 CFR 1910.141, including clean change rooms and shower facilities, shall be provided by the employer for the use of those employees, and the employer shall assure that the employees use the facilities provided.

(2) The employer shall assure that employees wearing protective clothing or equipment for protection from skin contact with liquid AN shall shower at the end of the work shift.

(3) The employer shall assure that, in the event of skin or eye exposure to liquid AN, the affected employee shall shower immediately to minimize the danger of skin absorption.

(4) The employer shall assure that employees working in the regulated area wash their hands and faces prior to eating.

(n) *Medical surveillance.*—(1) *General.* (i) The employer shall institute a program of medical surveillance for each employee who is or will be exposed to AN at or above the action level, without regard to the use of respirators. The employer shall provide each such employee with an opportunity for medical examinations and tests in accordance with this paragraph.

(ii) The employer shall assure that all medical examinations and procedures are performed by or under the supervision of a licensed physician, and that they shall be provided without cost to the employee.

(2) *Initial examinations.* At the time of initial assignment, or upon institution of the medical surveillance program, the employer shall provide each affected employee an opportunity for a medical examination, including at least the following elements:

(i) A work history and medical history with special attention to skin, respiratory, and gastrointestinal systems, and those nonspecific symptoms, such as headache, nausea, vomiting, dizziness, weakness, or other central nervous system dysfunctions that may be associated with acute or with chronic exposure to AN;

(ii) A complete physical examination giving particular attention to the peripheral and central nervous system, gastrointestinal system, respiratory system, skin, and thyroid;

(iii) A 14- by 17-inch posteroanterior chest X-ray; and

(iv) Further tests of the intestinal tract, including fecal occult blood screening, for all workers 40 years of age or older, and for any other affected employees for whom, in the opinion of the physician, such testing is appropriate.

(3) *Periodic examinations.* (i) The employer shall provide the examinations specified in paragraph (n)(2) of this section at least annually for all employees specified in paragraph (n)(1) of this section.

(ii) If an employee has not had the examination specified in paragraph (n)(2) of this section within 6 months preceding termination of employment, the employer shall make such examination available to the employee prior to such termination.

(4) *Additional examinations.* If the employee for any reason develops signs or symptoms which may be associated with exposure to AN, the employer shall provide an appropriate examination and emergency medical treatment.

(5) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this standard and its appendixes;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The employee's representative exposure level;

(iv) The employee's anticipated or estimated exposure level (for preplacement examinations or in cases of exposure due to an emergency);

(v) A description of any personal protective equipment used or to be used; and

(vi) Information from previous medical examinations of the affected employee, which is not otherwise available to the examining physician.

(6) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(A) The results of the medical examination and tests performed;

(B) The physician's opinion as to whether the employee has any detected medical condition(s) which would place the employee at an increased risk of material impairment of the employee's health from exposure to AN;

(C) Any recommended limitations upon the employee's exposure to AN or upon the use of protective clothing and equipment such as respirators; and (D) A statement that the employee has been informed by the physician of the results of the medical examination and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to AN.

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(o) *Employee information and training.* (1) *Training program.* (i) By January 2, 1979, the employer shall institute a training program for and assure the participaton of all employees exposed to AN above the action level, all employees whose exposures are maintained below the action level by engineering and work practice controls, and all employees subject to potential skin or eye contact with liquid AN.

(ii) Training shall be provided at the time of initial assignment, or upon institution of the training program, and at least annually thereafter, and the employer shall assure that each employee is informed of the following:

(A) The information contained in appendixes A and B;

(B) The quantity, location, manner of use, release, or storage of AN, and the specific nature of operations which could result in exposure to AN, as well as any necessary protective steps;

(C) The purpose, proper use, and limitations of respirators and protective clothing;

(D) The purpose and a description of the medical surveillance program required by paragraph (n) of this section;

(E) The emergency procedures developed, as required by paragraph (i) of this section;

(F) Engineering and work practice controls, their function, and the employee's relationship to these controls; and

(G) A review of this standard.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its appendixes readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(p) *Signs and labels.* (1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to, or in combination with, signs and labels required by this paragraph

(ii) The employer shall assure that no statement appears on or near any sign or label required by this paragraph which contradicts or detracts from the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all workplaces where AN concentrations exceed the permissible exposure limits. The signs shall bear the following legend:

DANGER

ACRYLONITRILE (AN)

CANCER HAZARD

AUTHORIZED PERSONNEL ONLY

RESPIRATORS MAY BE REQUIRED

(ii) The employer shall assure that signs required by this paragraph are illuminated and cleaned as necessary so that the legend is readily visible.

(3) *Labels.* (i) The employer shall assure that precautionary labels are affixed to all containers of liquid AN and AN-based materials not exempted under paragraph (a)(2) of this standard. The employer shall assure that the labels remain affixed when the materials are sold, distributed, or otherwise leave the employer's workplace.

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

CONTAINS ACRYLONITRILE (AN)

CANCER HAZARD

(q) *Recordkeeping.* (1) *Objective data for exempted operations.* (i) Where the processing, use, and handling of materials made from or containing AN are exempted pursuant to paragraph (a)(2) (ii) of this section, the employer shall establish and maintain an accurate record of objective data reasonably relied upon in support of the exemption.

(ii) This record shall include at least the following information:

(A) The material qualifying for exemption;

(B) The source of the objective data;

(C) The testing protocol, results of testing, and/or analysis of the material for the release of AN;

(D) A description of the operation exempted and how the data supports the exemption; and

(E) Other data relevant to the operations, materials, and processing covered by the exemption.

(iii) The employer shall maintain this record for the duration of the employer's reliance upon such objective data.

(2) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (e) of this section.

(ii) This record shall include:

(A) The dates, number, duration, and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(B) A description of the sampling and analytical methods used and the

data relied upon to establish that the methods used meet the accuracy and precision requirements of paragraph (e)(6) of this section;

(C) Type of respiratory protective devices worn, if any; and

(D) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least forty (40) years, or for the duration of employment plus twenty (20) years, whichever is longer.

(3) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance as required by paragraph (n) of this section.

(ii) This record shall include:

(A) A copy of the physician's written opinions;

(B) Any employee medical complaints related to exposure to AN;

(C) A copy of the information provided to the physician as required by paragraph (n)(5) of this section; and

(D) A copy of the employee's medical and work history.

(iii) The employer shall assure that this record be maintained for at least forty (40) years, or for the duration of employment plus twenty (20) years, whichever is longer.

(4) *Availability.* (i) The employer shall make all records required to be maintained by this section available, upon request, to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall make records required by paragraph (q)(1) and (q)(2) of this section available upon request, for examination and copying, to affected employees, former employees, or their designated representatives.

(iii) The employer shall make an employee's medical records required to be maintained by this section available upon request, for examination and copying, to the affected employee or former employee, or to a physician designated by the affected employee or former employee.

(5) *Transfer of records.* (i) Whenever the employer ceases to do business, the successor employer shall receive and retain all records required to be maintained by this section for the prescribed period.

(ii) Whenever the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, these records shall be transmitted to the Director.

(iii) At the expiration of the retention period for the records required to be maintained pursuant to this section, the employer shall notify the Director at least 3 months prior to the disposal of the records, and shall transmit them to the Director upon request.

(r) *Observation of monitoring.* (1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to AN conducted pursuant to paragraph (e) of this section.

(2) *Observation procedures.* (i) Whenever observation of the monitoring of employee exposure to AN requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing and equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring, observers shall be entitled:

(A) To receive an explanation of the measurement procedures;

(B) To observe all steps related to the measurement of airborne concentrations of AN performed at the place of exposure; and

(C) To record the results obtained.

(s) *Effective date.*

(1) This section shall become effective November 2, 1978.

(2) Monitoring and medical surveillance conducted since January 17, 1978, under the provisions of the emergency temporary standard may be relied upon by the employer to meet the initial monitoring and initial medical surveillance requirements of this section.

(3) Training programs must be implemented by January 2, 1979.

(4) Engineering and work practice controls required by paragraph (g) of this section shall be implemented no later than November 2, 1980.

(t) *Appendixes.* The information contained in the appendixes is not intended, by itself, to create any additional obligations not otherwise imposed, or to detract from any obligation.

APPENDIX A—SUBSTANCE SAFETY DATA SHEET FOR ACRYLONITRILE

I. SUBSTANCE IDENTIFICATION

A. Substance: Acrylonitrile (CH_2=CHCN).

B. Synonyms: Propenenitrile; vinyl cyanide; cyanoethylene; AN; VCN; acrylon; carbacryl; fumigrain; ventox.

C. Acrylonitrile can be found as a liquid or vapor, and can also be found in polymer resins, rubbers, plastics, polyols, and other polymers having acrylonitrile as a raw or intermediate material.

D. AN is used in the manufacture of acrylic and modiacrylic fibers, acrylic plastics and resins, speciality polymers, nitrile rubbers, and other organic chemicals. It has also been used as a fumigant.

E. Appearance and odor: Colorless to pale yellow liquid with a pungent odor which can only be detected at concentrations above the permissible exposure level, in a range of 13–19 parts AN per million parts of air (13–19 ppm).

F. Permissible exposure: Exposure may not exceed either:

1. Two parts AN per million parts of air (2 ppm) averaged over the 8-hour workday; or

2. Ten parts AN per million parts of air (10 ppm) averaged over any 15-minute period in the workday.

3. In addition, skin and eye contact with liquid AN is prohibited.

II. HEALTH HAZARD DATA

A. Acrylonitrile can affect your body if you inhale the vapor (breathing), if it comes in contact with your eyes or skin, or if you swallow it. It may enter your body through your skin.

B. Effects of overexposure: 1. Short-term exposure: Acrylonitrile can cause eye irritation, nausea, vomiting, headache, sneezing, weakness, and light-headedness. At high concentrations, the effects of exposure may go on to loss of consciousness and death. When acrylonitrile is held in contact with the skin after being absorbed into shoe leather or clothing, it may produce blisters following several hours of no apparent effect. Unless the shoes or clothing are removed immediately and the area washed, blistering will occur. Usually there is no pain or inflammation associated with blister formation.

2. Long-term exposure: Acrylonitrile has been shown to cause cancer in laboratory animals and has been associated with higher incidences of cancer in humans. Repeated or prolonged exposure of the skin to acrylonitrile may produce irritation and dermatitis.

3. Reporting signs and symptoms: You should inform your employer if you develop any signs or symptoms and suspect they are caused by exposure to acrylonitrile.

III. EMERGENCY FIRST AID PROCEDURES

A. Eye exposure: If acrylonitrile gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.

B. Skin exposure: If acrylonitrile gets on your skin, immediately wash the contaminated skin with water. If acrylonitrile soaks through your clothing, especially your shoes, remove the clothing immediately and wash the skin with water. If symptoms occur after washing, get medical attention immediately. Thoroughly wash the clothing before reusing. Contaminated leather shoes or other leather articles should be discarded.

C. Inhalation: If you or any other person breathes in large amounts of acrylonitrile, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Keep the affected person warm and at rest. Get medical attention as soon as possible.

D. Swallowing: When acrylonitrile has been swallowed, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him touch the back of his

throat with his finger. Do not make an unconscious person vomit. Get medical attention immediately.

E. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, notify someone else and put into effect the established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the emergency equipment before the need arises.

F. Special first aid procedures: First aid kits containing an adequate supply (at least two dozen) of amyl nitrite pearls, each containing 0.3 ml, should be maintained at each site where acrylonitrile is used. When a person is suspected of receiving an overexposure to acrylonitrile, immediately remove that person from the contaminated area using established rescue procedures. Contaminated clothing must be removed and the acrylonitrile washed from the skin immediately. Artificial respiration should be started at once if breathing has stopped. If the person is unconscious, amyl nitrite may be used as an antidote by a properly trained individual in accordance with established emergency procedures. Medical aid should be obtained immediately.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

A. Respirators: You may be required to wear a respirator for nonroutine activites, in emergencies, while your employer is in the process of reducing acrylonitrile exposures through engineering controls, and in areas where engineering controls are not feasible. If respirators are worn, they must have a Mine Safety and Health Administration (MSHA or MESA) or National Institute for Occupational Safety and Health (NIOSH) label of approval for use with organic vapors. (Older respirators may have a Bureau of Mines approval label.) For effective protection, respirators must fit your face and head snugly. Respirators should not be loosened or removed in work situations where their use is required.

Acrylonitrile does not have a detectable odor except at levels above the permissible exposure limits. Do not depend on odor to warn you when a respirator cartridge or canister is exhausted. Cartridges or canisters must be changed daily or before the end-of-service-life, whichever comes first. Reuse of these may allow acrylonitrile to gradually filter through the cartridge and cause exposures which you cannot detect by odor. If you can smell acrylonitrile while wearing a respirator, proceed immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. Supplied-air suits: In some work situations, the wearing of supplied-air suits may be necessary. Your employer must instruct you in their proper use and operation.

C. Protective clothing: You must wear impervious clothing, gloves, face shield, or other appropriate protective clothing to prevent skin contact with liquid acrylonitrile. Where protective clothing is required, your employer is required to provide clean garments to you as necessary to assume that the clothing protects you adequately.

Replace or repair impervious clothing that has developed leaks.

Acrylonitrile should never be allowed to remain on the skin. Clothing and shoes which are not impervious to acrylonitrile should not be allowed to become contaminated with acrylonitrile, and if they do the clothing and shoes should be promptly removed and decontaminated. The clothing should be laundered or discarded after the AN is removed. Once acrylonitrile penetrates shoes or other leather articles, they should not be worn again.

D. Eye protection: You must wear splashproof safety goggles in areas where liquid acrylonitrile may contact your eyes. In addition, contact lenses should not be worn in areas where eye contact with acrylonitrile can occur.

V. PRECAUTIONS FOR SAFE USE, HANDLING, AND STORAGE

A. Acrylonitrile is a flammable liquid, and its vapors can easily form explosive mixtures in air.

B. Acrylonitrile must be stored in tightly closed containers in a cool, well-ventilated area, away from heat, sparks, flames, strong oxidizers (especially bromine), strong bases, copper, copper alloys, ammonia, and amines.

C. Sources of ignition such as smoking and open flames are prohibited wherever acrylonitrile is handled, used, or stored in a manner that could create a potential fire or explosion hazard.

D. You should use non-sparking tools when opening or closing metal containers of acrylonitrile, and containers must be bonded and grounded when pouring or transferring liquid acrylonitrile.

E. You must immediately remove any nonimpervious clothing that becomes wetted with acrylonitrile, and this clothing must not be reworn until the acrylonitrile is removed from the clothing.

F. Impervious clothing wet with liquid acrylonitrile can be easily ignited. This clothing must be washed down with water before you remove it.

G. If your skin becomes wet with liquid acrylonitrile, you must promptly and thoroughly wash or shower with soap or mild detergent to remove any acrylonitrile from your skin.

H. You must not keep food, beverages, or smoking materials, nor are you permitted to eat or smoke in regulated areas where acrylonitrile concentrations are above the permissible exposure limits.

I. If you contact liquid acrylonitrile, you must wash your hands thoroughly with soap or mild detergent and water before eating, smoking, or using toilet facilities.

J. Fire extinguishers and quick drenching facilities must be readily available, and you should know where they are and how to operate them.

K. Ask your supervisor where acrylonitrile is used in your work area and for any additional plant safety and health rules.

VI. ACCESS TO INFORMATION

A. Each year, your employer is required to inform you of the information contained in this Substance Safety Data Sheet for acrylonitrile. In addition, your employer must instruct you in the proper work practices for using acrylonitrile, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to acrylonitrile. You or your representative has the right to observe employee measurements and to record the results obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he or she is required to inform you of the actions which are being taken to reduce your exposure to within permissible exposure limits.

C. Your employer is required to keep records of your exposures and medical examinations. These records must be kept by the employer for at least forty (40) years or for the period of your employment plus twenty (20) years, whichever is longer.

D. Your employer is required to release your exposure and medical records to your physician upon your written request.

APPENDIX B—SUBSTANCE TECHNICAL GUIDELINES FOR ACRYLONITRILE

I. PHYSICAL AND CHEMICAL DATA

A. Substance identification: 1. Synonyms: AN; VCN; vinyl cyanide; propenenitrile; cyanoethylene; Acrylon; Carbacryl; Fumigrain; Ventox.

2. Formula: $CH_2=CHCN$.

3. Molecular weight: 53.1.

B. Physical data: 1. Boiling point (760 mm Hg): 77.3°C (171° F);

2. Specific gravity (water=1): 0.81 (at 20° C or 68° F);

3. Vapor density (air=1 at boiling point of acrylonitrile): 1.83;

4. Melting point: −83° C (−117° F);

5. Vapor pressure (@20° F): 83 mm Hg;

6. Solubility in water, percent by weight @20° C (68° F): 7.35;

7. Evaporation rate (Butyl Acetate=1): 4.54; and

8. Appearance and odor: Colorless to pale yellow liquid with a pungent odor at concentrations above the permissible exposure level. Any detectable odor of acrylonitrile may indicate overexposure.

II. FIRE, EXPLOSION, AND REACTIVITY HAZARD DATA

A. Fire: 1. Flash point: −1° C (30° F) (closed cup).

2. Autoignition temperature: 481° C (898° F).

3. Flammable limits air, percent by volume: Lower: 3, Upper: 17.

4. Extinguishing media: Alcohol foam, carbon dioxide, and dry chemical.

5. Special fire-fighting procedures: Do not use a solid stream of water, since the stream will scatter and spread the fire. Use water to cool containers exposed to a fire.

6. Unusual fire and explosion hazards: Acrylonitrile is a flammable liquid. Its vapors can easily form explosive mixtures with air. All ignition sources must be controlled where acrylonitrile is handled, used, or stored in a manner that could create a potential fire or explosion hazard. Acrylonitrile vapors are heavier than air and may travel along the ground and be ignited by open flames or sparks at locations remote from the site at which acrylonitrile is being handled.

7. For purposes of compliance with the requirements of 29 CFR 1910.106, acrylonitrile is classified as a class IB flammable liquid. For example, 7,500 ppm, approximately one-fourth of the lower flammable limit, would be considered to pose a potential fire and explosion hazard.

8. For purposes of compliance with 29 CFR 1910.157, acrylonitrile is classified as a Class B fire hazard.

9. For purpose of compliance with 29 CFR 1919.309, locations classified as hazardous due to the presence of acrylonitrile shall be Class I, Group D.

B. Reactivity:

1. Conditions contributing to instability: Acrylonitrile will polymerize when hot, and the additional heat liberated by the polymerization may cause containers to explode. Pure AN may self-polymerize, with a rapid build-up of pressure, resulting in an explosion hazard. Inhibitors are added to the commercial product to prevent self-polymerization.

2. Incompatibilities: Contact with strong oxidizers (especially bromine) and strong bases may cause fires and explosions. Contact with copper, copper alloys, ammonia, and amines may start serious decomposition.

3. Hazardous decomposition products: Toxic gases and vapors (such as hydrogen cyanide, oxides of nitrogen, and carbon monoxide) may be released in a fire involving acrylonitrile and certain polymers made from acrylonitrile.

4. Special precautions: Liquid acrylonitrile will attack some forms of plastics, rubbers, and coatings.

III. SPILL, LEAK, AND DISPOSAL PROCEDURES

A. If acrylonitrile is spilled or leaked, the following steps should be taken:

1. Remove all ignition sources.

2. The area should be evacuated at once and re-entered only after the area has been thoroughly ventilated and washed down with water.

3. If liquid acrylonitrile or polymer intermediate, collect for reclamation or absorb in paper, vermiculite, dry sand, earth, or similar material, or wash down with water into process sewer system.

B. Persons not wearing protective equipment should be restricted from areas of spills or leaks until clean-up has been completed.

C. Waste disposal methods: Waste material shall be disposed of in a manner that is not hazardous to employees or to the general population. Spills of acrylonitrile and flushing of such spills shall be channeled for appropriate treatment or collection for disposal. They shall not be channeled directly into the sanitary sewer system. In selecting the method of waste disposal, applicable local, State, and Federal regulations should be consulted.

IV. MONOTORING AND MEASUREMENT PROCEDURES

A. Exposure above the Permissible Exposure Limit:

1. Eight-hour exposure evaluation: Measurements taken for the purpose of determining employee exposure under this section are best taken so that the average 8-hour exposure may be determined from a single 8-hour sample or two (2) 4-hour samples. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee.)

2. Ceiling evaluation: Measurements taken for the purpose of determining employee exposure under this section must be taken during periods of maximum expected airborne concentrations of acrylonitrile in the employee's breathing zone. A minimum of three (3) measurements should be taken on one work shift. The average of all measurements taken is an estimate of the employee's ceiling exposure.

3. Monitoring techniques: The sampling and analysis under this section may be performed by collecting the acrylonitrile vapor on charcoal adsorption tubes or other composition adsorption tubes, with subsequent chemical analysis. Sampling and analysis may also be performed by instruments such as real-time continuous monotoring systems, portable direct-reading instruments, or passive dosimeters. Analysis of resultant samples should be by gas chromatograph.

Appendix D lists methods of sampling and analysis which have been tested by NIOSH and OSHA for use with acrylonitrile. NIOSH and OSHA have validated modifications of NIOSH Method S-156 (See Appendix D) under laboratory conditions for concentrations below 1 ppm. The employer has the obligation of selecting a monitoring method which meets the accuracy and precision requirements of the standard under his unique field conditions. The standard requires that methods of monitoring must be accurate, to a 95-percent confidence level, to ±35-percent for concentrations of AN at or above 2 ppm, and to ±50-percent for concentrations below 2 ppm. In addition to the methods described in Appendix D, there are numerous other methods available for monitoring for AN in the workplace. Details on these other methods have been submitted by various companies to the rulemaking record, and are available at the OSHA Docket Office.

B. Since many of the duties relating to employee exposure are dependent on the results of monitoring and measuring procedures, employers shall assure that the evaluation of employee exposures is performed by a competent industrial hygienist or other technically qualified person.

V. PROTECTIVE CLOTHING

Employees shall be provided with and required to wear appropriate protective clothing to prevent any possibility of skin contact with liquid AN. Because acrylonitrile is absorbed through the skin, it is important to prevent skin contact with liquid AN. Protective clothing shall include impermeable coveralls or similar full-body work clothing, gloves, head-coverings, as appropriate to protect areas of the body which may come in contact with liquid AN.

Employers should ascertain that the protective garments are impermeable to acrylonitrile. Non-impermeable clothing and shoes should not be allowed to become contaminated with liquid AN. If permeable clothing does become contaminated, it should be promptly removed, placed in a regulated area for removal of the AN, and not worn again until the AN is removed. If leather footwear or other leather garments become wet from acrylonitrile, they should be replaced and not worn again, due to the ability of leather to absorb acrylonitrile and hold it against the skin. Since there is no pain associated with the blistering which may result from skin contact with liquid AN, it is essential that the employee be informed of this hazard so that he or she can be protected.

Any protective clothing which has developed leaks or is otherwise found to be defective shall be repaired or replaced. Clean protective clothing shall be provided to the employee as necessary to assure its protectiveness. Whenever impervious clothing becomes wet with liquid AN, it shall be washed down with water before being removed by the employee. Employees are also required to wear splash-proof safety goggles where there is any possibility of acrylonitrile contacting the eyes.

VI. HOUSEKEEPING AND HYGIENE FACILITIES

For purposes of complying with 29 CFR 1910.141, the following items should be emphasized:

A. The workplace should be kept clean, orderly, and in a sanitary condition. The employer is required to institute a leak and spill detection program for operations involving liquid AN in order to detect sources of fugitive AN emissions.

B. Dry sweeping and the use of compressed air is unsafe for the cleaning of floors and other surfaces where liquid AN may be found.

C. Adequate washing facilities with hot and cold water are to be provided, and maintained in a sanitary condition. Suitable cleansing agents are also to be provided to assure the effective removal of acrylonitrile from the skin.

D. Change or dressing rooms with individual clothes storage facilities must be provided to prevent the contamination of street clothes with acrylonitrile. Because of the hazardous nature of acrylonitrile, contaminated protective clothing should be placed in a regulated area designated by the employer for removal of the AN before the clothing is laundered or disposed of.

VII. MISCELLANEOUS PRECAUTIONS

A. Store acrylonitrile in tightly-closed containers in a cool, well-ventilated area and take necessary precautions to avoid any explosion hazard.

B. High exposures to acrylonitrile can occur when transferring the liquid from one container to another.

C. Non-sparking tools must be used to open and close metal acrylonitrile containers. These containers must be effectively grounded and bonded prior to pouring.

D. Never store uninhibited acrylonitrile.

E. Acrylonitrile vapors are not inhibited. They may form polymers and clog vents of storage tanks.

F. Use of supplied-air suits or other impervious coverings may be necessary to prevent skin contact with and provide respiratory protection from acrylonitrile where the concentration of acrylonitrile is unknown or is above the ceiling limit. Supplied-air suits should be selected, used, and maintained under the immediate supervision of persons knowledgeable in the limitations and potential life-endangering characteristics of supplied-air suits.

G. Employers shall advise employees of all areas and operations where exposure to acrylonitrile could occur.

VIII. COMMON OPERATIONS

Common operations in which exposure to acrylonitrile is likely to occur include the following: Manufacture of the acrylonitrile monomer; synthesis of acrylic fibers, ABS, SAN, and nitrile barrier plastics and resins, nitrile rubber, surface coatings, specialty chemicals, use as a chemical intermediate, use as a fumigant and in the cyanoethylation of cotton.

APPENDIX C—MEDICAL SURVEILLANCE GUIDELINES FOR ACRYLONITRILE

I. ROUTE OF ENTRY

Inhalation; skin absorption; ingestion.

II. TOXICOLOGY

Acrylonitrile vapor is an asphyxiant due to inhibitory action on metabolic enzyme

systems. Animals exposed to 75 or 100 ppm for 7 hours have shown signs of anoxia; in some animals which died at the higher level, cyanomethemoglobin was found in the blood. Two human fatalities from accidental poisoning have been reported; one was caused by inhalation of an unknown concentration of the vapor, and the other was thought to be caused by skin absorption or inhalation. Most cases of intoxication from industrial exposure have been mild, with rapid onset of eye irritation, headache, sneezing, and nausea. Weakness, lightheadedness, and vomiting may also occur. Exposure to high concentrations may produce profound weakness, asphyxia, and death. The vapor is a severe eye irritant. Prolonged skin contract with the liquid may result in absorption with systemic effects, and in the formation of large blisters after a latent period of several hours. Although there is usually little or no pain or inflammation, the affected skin resembles a second-degree thermal burn. Solutions spilled on exposed skin, or on areas covered only by a light layer of clothing, evaporate rapidly, leaving no irritation, or, at the most, mild transient redness. Repeated spills on exposed skin may result in dermatitis due to solvent effects.

Results after 1 year of a planned 2-year animal study on the effects of exposure to acrylonitrile have indicated that rats ingesting as little as 35 ppm in their drinking water develop tumors of the central nervous system. The interim results of this study have been supported by a similar study being conducted by the same laboratory, involving exposure of rats by inhalation of acrylonitrile vapor, which has shown similar types of tumors in animals exposed to 80 ppm.

In addition, the preliminary results of an epidemiological study being performed by duPont on a cohort of workers in their Camden, S.C. acrylic fiber plant indicate a statistically significant increase in the incidence of colon and lung cancers among employees exposed to acrylonitrile.

III. SIGNS AND SYMPTOMS OF ACUTE OVEREXPOSURE

Asphyxia and death can occur from exposure to high concentrations of acrylonitrile. Symptoms of overexposure include eye irritation, headache, sneezing, nausea and vomiting, weakness, and light-headedness. Prolonged skin contact can cause blisters on the skin with appearance of a second-degree burn, but with little or no pain. Repeated skin contact may produce scaling dermatitis.

IV. TREATMENT OF ACUTE OVEREXPOSURE

Remove employee from exposure. Immediately flush eyes with water and wash skin with soap or mild detergent and water. If AN has been swallowed, and person is conscious, induce vomiting. Give artificial resuscitation if indicated. More severe cases, such as those associated with loss of consciousness, may be treated by the intravenous administration of sodium nitrite, followed by sodium thiosulfate, although this is not as effective for acrylonitrile poisoning as for inorganic cyanide poisoning.

V. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. As noted above, exposure to acrylonitrile has been linked to increased incidence of cancers of the colon and lung in employees of the duPont acrylic fiber plant in Camden, S.C. In addition, the animal testing of acrylonitrile has resulted in the development of cancers of the central nervous system in rats exposed by either inhalation or ingestion. The physician should be aware of the findings of these studies in evaluating the health of employees exposed to acrylonitrile.

Most reported acute effects of occupational exposure to acrylonitrile are due to its ability to cause tissue anoxia and asphyxia. The effects are similar to those caused by hydrogen cyanide. Liquid acrylonitrile can be absorbed through the skin upon prolonged contact. The liquid readily penetrates leather, and will produce burns of the feet if footwear contaminated with acrylonitrile is not removed.

It is important for the physician to become familiar with the operating conditions in which exposure to acrylonitrile may occur. Those employees with skin diseases may not tolerate the wearing of whatever protective clothing may be necessary to protect them from exposure. In addition, those with chronic respiratory disease may not tolerate the wearing of negative-pressure respirators.

B. Surveillance and screening. Medical histories and laboratory examinations are required for each employee subject to exposure to acrylonitrile above the action level. The employer must screen employees for history of certain medical conditions which might place the employee at increased risk from exposure.

1. *Central nervous system dysfunction.* Acute effects of exposure to acrylonitrile generally involve the central nervous system. Symptoms of acrylonitrile exposure include headache, nausea, dizziness, and general weakness. The animal studies cited above suggest possible carcinogenic effects of acrylonitrile on the central nervous system, since rats exposed by either inhalation or ingestion have developed similar CNS tumors.

2. *Respiratory disease.* The du Pont data indicate an increased risk of lung cancer among employees exposed to acrylonitrile.

3. *Gastrointestinal disease.* The du Pont data indicate an increased risk of cancer of the colon among employees exposed to acrylonitrile. In addition, the animal studies show possible tumor production in the stomachs of the rats in the ingestion study.

4. *Skin disease.* Acrylonitrile can cause skin burns when prolonged skin contact with the liquid occurs. In addition, repeated skin contact with the liquid can cause dermatitis.

5. *General.* The purpose of the medical procedures outlined in the standard is to establish a baseline for future health monitoring. Persons unusually susceptible to the effects of anoxia or those with anemia would be expected to be at increased risk. In addition to emphasis on the CNS, respiratory and gastro-intestinal systems, the cardiovascular system, liver, and kidney function should also be stressed.

APPENDIX D.—SAMPLING AND ANALYTICAL METHODS FOR ACRYLONITRILE

There are many methods available for monitoring employee exposures to acrylonitrile. Most of these involve the use of charcoal tubes and sampling pumps, with analysis by gas chromatograph. The essential differences between the charcoal tube methods include, among others, the use of different desorbing solvents, the use of different lots of charcoal, and the use of different equipment for analysis of the samples.

Besides charcoal, considerable work has been performed on methods using porous polymer sampling tubes and passive dosimeters. In addition, there are several portable gas analyzers and monitoring units available on the open market.

This appendix contains details for the methods which have been tested at OSHA Analytical Laboratory in Salt Lake City, and NIOSH in Cincinnati. Each is a variation on NIOSH Method S-156, which is also included for reference. This does not indicate that these methods are the only ones which will be satisfactory. There also may be workplace situations in which these methods are not adequate, due to such factors as high humidity. Copies of the other methods available to OSHA are available in the rulemaking record, and may be obtained from the OSHA Docket Office. These include the Union Carbide, Monsanto, Dow Chemical and Dow Badische methods, as well as NIOSH Method P & CAM 127.

Employers who note problems with sample breakthrough should try larger charcoal tubes. Tubes of larger capacity are available, and are often used for sampling vinyl chloride. In addition, lower flow rates and shorter sampling times should be beneficial in minimizing breakthrough problems.

Whatever method the employer chooses, he must assure himself of the method's accuracy and precision under the unique conditions present in his workplace.

NIOSH METHOD S-156 (UNMODIFIED)

Analyte: Acrylonitrile.
Matrix: Air.
Procedure: Absorption on charcoal, desorption with methanol, GC.

1. *Principle of the method* (Reference 11.1).

1.1 A known volume of air is drawn through a charcoal tube to trap the organic vapors present.

1.2 The charcoal in the tube is transferred to a small, stoppered sample container, and the analyte is desorbed with methanol.

1.3 An aliquot of the desorbed sample is injected into a gas chromatograph.

1.4 The area of the resulting peak is determined and compared with areas obtained for standards.

2. *Range and sensitivity.*

2.1 This method was validated over the range of 17.5-70.0 mg/cu m at an atmospheric temperature and pressure of 22° C and 760 mm Hg, using a 20-liter sample. Under the conditions of sample size (20 liters) the probable useful range of this method is 4.5-135 mg-cu m. The method is capable of measuring much smaller amounts if the desorption efficiency is adequate. Desorption efficiency must be determined over the range used.

2.2 The upper limit of the range of the method is dependent on the adsorptive capacity of the charcoal tube. This capacity varies with the concentrations of acrylonitrile and other substances in the air. The first section of the charcoal tube was found to hold at least 3.97 mg of acrylonitrile when a test atmosphere containing 92.0 mg/cu m of acrylonitrile in air was sampled 0.18 liter per minute for 240 minutes; at that time the concentration of acrylonitrile in the effluent was less than 5 percent of that in the influent. (The charcoal tube consists of two sections of activated charcoal sepa-

rated by a section of urethane foam. See section 6.2.) If a particular atmosphere is suspected of containing a large amount of contaminant, a smaller sampling volume should be taken.

3. *Interference.*

3.1 When the amount of water in the air is so great that condensation actually occurs in the tube, organic vapors will not be trapped efficiently. Preliminary experiments using toluene indicate that high humidity severely decreases the breakthrough volume.

3.2 When interfering compounds are known or suspected to be present in the air, such information, including their suspected identities, should be transmitted with the sample.

3.3 It must be emphasized that any compound which has the same retention time as the analyte at the operating conditions described in this method is an interference. Retention time data on a single column cannot be considered proof of chemical identity.

3.4 If the possibility of interference exists, separation conditions (column packing, temperature, etc.) must be changed to circumvent the problem.

4. *Precision and accuracy.*

4.1 The Coefficient of Variation (CV_T) for the total analytical and sampling method in the range of 17.5-70.0 mg/cu m was 0.073. This value corresponds to a 3.3 mg/cu m standard deviation at the (previous) OSHA standard level (20 ppm). Statistical information and details of the validation and experimental test procedures can be found in Reference 11.2.

4.2 On the average the concentrations obtained at the 20 ppm level using the overall sampling and analytical method were 6.0 percent lower than the "true" concentrations for a limited number of laboratory experiments. Any difference between the "found" and "true" concentrations may not represent a bias in the sampling and analytical method, but rather a random variation from the experimentally determined "true" concentration. Therefore, no recovery correction should be applied to the final result in section 10.5.

5. *Advantages and disadvantages of the method.*

5.1 The sampling device is small, portable, and involves no liquids. Interferences are minimal, and most of those which do occur can be eliminated by altering chromatographic conditions. The tubes are analyzed by means of a quick, instrumental method.

The method can also be used for the simultaneous analysis of two or more substances suspected to be present in the same sample by simply changing gas chromatographic conditions.

5.2 One disadvantage of the method is that the amount of sample which can be taken is limited by the number of milligrams that the tube will hold before overloading. When the sample value obtained for the backup section of the charcoal tube exceeds 25 percent of that found on the front section, the possibility of sample loss exists.

5.3 Furthermore, the precision of the method is limited by the reproducibility of the pressure drop across the tubes. This drop will affect the flow rate and cause the volume to be imprecise, because the pump is usually calibrated for one tube only.

6. *Apparatus.*

6.1 A calibrated personal sampling pump whose flow can be determined within ±5 percent at the recommended flow rate. (Reference 11.3).

6.2 Charcoal tubes: Glass tubes with both ends flame sealed, 7 cm long with a 6-mm O.D. and a 4-mm I.D., containing 2 sections of 20/40 mesh activated charcoal separated by a 2-mm portion of urethane foam. The activated charcoals prepared from coconut shells and is fired at 600° C prior to packing. The adsorbing section contains 100 mg of charcoal, the backup section 50 mg. A 3-mm portion of urethane foam is placed between the outlet end of the tube and the backup section. A plug of silicated glass wool is placed in front of the adsorbing section. The pressure drop across the tube must be less than 1 inch of mercury at a flow rate of 1 liter per minute.

6.3 Gas chromatograph equipped with a flame ionization detector.

6.4 Column (4-ft × ¼-in stainless steel) packed with 50/80 mesh Poropak, type Q.

6.5 An electronic integrator or some other suitable method for measuring peak areas.

6.6 Two-milliliter sample containers with glass stopers or Teflon-lined caps. If an automatic sample injector is used, the associated vials may be used.

6.7 Microliter syringes: 10-microliter, and other convenient sizes for making standards.

6.8 Pipets: 1.0-ml delivery pipets.

6.9 Volumetric flask: 10-ml or convenient sizes for making standard solutions.

7. *Reagents.*

7.1 Chromatographic quality methanol.

7.2 Acrylonitrile, reagent grade.

7.3 Hexane, reagent grade.

7.4 Purified nitrogen.

7.5 Prepurified hydrogen.

7.6 Filtered compressed air.

8. *Procedure.*

8.1 Cleaning of equipment. All glassware used for the laboratory analysis should be detergent washed and thoroughly rinsed with tap water and distilled water.

8.2 Calibration of personal pumps. Each personal pump must be calibrated with a representative charcoal tube in the line. This will minimize errors associated with uncertainties in the sample volume collected.

8.3 Collection and shipping of samples.

8.3.1 Immediately before sampling, break the ends of the tube to provide an opening at least one-half the internal diameter of the tube (2 mm).

8.3.2 The smaller section of charcoal is used as a backup and should be positioned nearest the sampling pump.

8.3.3 The charcoal tube should be placed in a vertical direction during sampling to minimize channeling through the charcoal.

8.3.4 Air being sampled should not be passed through any hose or tubing before entering the charcoal tube.

8.3.5 A maximum sample size of 20 liters is recommended. Sample at a flow of 0.20 liter per minute or less. The flow rate should be known with an accuracy of at least ±5 percent.

8.3.6 The temperature and pressure of the atmosphere being sampled should be recorded. If pressure reading is not available, record the elevation.

83.7 The charcoal tubes should be capped with the supplied plastic caps immediately after sampling. Under no circumstances should rubber caps be used.

8.3.8 With each batch of 10 samples submit one tube from the same lot of tubes which was used for sample collection and which is subjected to exactly the same handling as the samples except that no air is drawn through it. Label this as a blank.

8.3.9 Capped tubes should be packed tightly and padded before they are shipped to minimize tube breakage during shipping.

8.3.10 A sample of the bulk material should be submitted to the laboratory in a glass container with a Teflon-lined cap. This sample should not be transported in the same container as the charcoal tubes.

8.4 *Analysis of samples.*

8.4.1 Preparation of samples. In preparation for analysis, each charcoal tube is scored with a file in front of the first section of charcoal and broken open. The glass wool is removed and discarded. The charcoal in the first (larger) section is transferred to a 2-ml stoppered sample container. The separating section of foam is removed and discarded; the second section is transferred to another stoppered container. These two sections are analyzed separately.

8.4.2 Desorption of samples. Prior to analysis, 1.0 ml of methanol is pipetted into each sample container. Desorption should be done for 30 minutes. Tests indicate that this is adequate if the sample is agitated occasionally during this period. If an automatic sample injector is used, the sample vials should be capped as soon as the solvent is added to minimize volatilization.

8.4.3 GC conditions. The typical operating conditions for the gas chromatograph are:

1. 50 ml/min (60 psig) nitrogen carrier gas flow.

2. 65 ml/min (24 psig) hydrogen gas flow to detector.

3. 500 ml/min (50 psig) air flow to detector.

4. 235° C injector temperature.

5. 255° C manifold temperature (detector).

6. 155° C column temperature.

8.4.4 Injection. The first step in the analysis is the injection of the sample into the gas chromatograph. To eliminate difficulties arising from blowback or distillation within the syringe needle, one should employ the solvent flush injection technique. The 10-microliter syringe is first flushed with solvent several times to wet the barrel and plunger. Three microliters of solvent are drawn into the syringe to increase the accuracy and reproducibility of the injected sample volume. The needle is removed from the solvent, and the plunger is pulled back about 0.2 microliter to separate the solvent flush from the sample with a pocket of air to be used as a marker. The needle is then immersed in the sample, and a 5-microliter aliquot is withdrawn, taking into consideration the volume of the needle, since the sample in the needle will be completely injected. After the needle is removed from the sample and prior to injection, the plunger is pulled back 1.2 microliters to minimize evaporation of the sample from the tip of the needle. Observe that the sample occupies 4.9-5.0 microliters in the barrel of the syringe. Duplicate injections of each sample and standard should be made. No more than a 3 percent difference in area is to be expected. An automatic sample injector can be used if it is shown to give reproducibility at least as good as the solvent flush method.

8.4.5 Measurement of area. The area of the sample peak is measured by an electron-

ic integrator or some other suitable form of area measurement, and preliminary results are read from a standard curve prepared as discussed below.

8.5. *Determination of desorption efficiency.*

8.5.1 Importance of determination. The desorption efficiency of a particular compound can vary from one laboratory to another and also from one batch of charcoal to another. Thus, it is necessary to determine at least once the percentage of the specific compound that is removed in the desorption process, provided the same batch of charcoal is used.

8.5.2 Procedure for determining desorption efficiency. Activated charcoal equivalent to the amount in the first section of the sampling tube (100 mg) is measured into a 2.5 in, 4-mm I.D. glass tube, flame sealed at one end. This charcoal must be from the same batch as that used in obtaining the samples and can be obtained from unused charcoal tubes. The open end is capped with Parafilm. A known amount of hexane solution of acrylonitrile containing 0.239 g/ml is injected directly into the activated charcoal with a microliter syringe, and tube is capped with more Parafilm. When using an automatic sample injector, the sample injector vials, capped with Teflon-faced septa, may be used in place of the glass tubes.

The amount injected is equivalent to that present in a 20-liter air sample at the selected level.

Six tubes at each of three levels (0.5X, 1X, and 2X of the standard) are prepared in this manner and allowed to stand for at least overnight to assure complete adsorption of the analyte onto the charcoal. These tubes are referred to as the sample. A parallel blank tube should be treated in the same manner except that no sample is added to it. The sample and blank tubes are desorbed and analyzed in exactly the same manner as the sampling tube described in section 8.4.

Two or three standards are prepared by injecting the same volume of compound into 1.0 ml of methanol with the same syringe used in the preparation of the samples. These are analyzed with the samples.

The desorption efficiency (D.E.) equals the average weight in mg recovered from the tube divided by the weight in mg added to the tube, or

D.E. = Average weight recovered (mg)/weight added (mg)

The desorption efficiency is dependent on the amount of analyte collected on the charcoal. Plot the desorption efficiency versus weight of analyte found. This curve is used in section 10.4 to correct for adsorption losses.

9. *Calibration and standards.*

It is convenient to express concentration of standards in terms of mg/1.0 ml methanol, because samples are desorbed in this amount of methanol. The density of the analyte is used to convert mg into microliters for easy measurement with a microliter syringe. A series of standards, varying in concentration over the range of interest, is prepared and analyzed under the same GC conditions and during the same time period as the unknown samples. Curves are established by plotting concentration in mg/1.0 ml versus peak area.

NOTE.—Since no internal standard is used in the method, standard solutions must be analyzed at the same time that the sample analysis is done. This will minimize the effect of known day-to-day variations and variations during the same day of the FID response.

10. *Calculations.*

10.1 Read the weight, in mg, corresponding to each peak area from the standard curve. No volume corrections are needed, because the standard curve is based on mg/1.0 ml methanol and the volume of sample injected is identical to the volume of the standards injected.

10.2 Corrections for the blank must be made for each sample.

mg = mg sample − mg blank

Where:

mg sample = mg found in front section of sample tube.

mg sample = mg found in front section of blank tube.

A similar procedure is followed for the backup sections.

10.3 Add the weights found in the front and backup sections to get the total weight in the sample.

10.4 Read the desorption efficiency from the curve (see sec. 8.5.2) for the amount found in the front section. Divide the total weight by this desorption efficiency to obtain the corrected mg/sample.

Corrected mg/sample = Total weight/D.E.

10.5 The concentration of the analyte in the air sampled can be expressed in mg/cu m.

mg/cu m = Corrected mg (section 10.4) × 1,000 (liter/cu m)/air volume sampled (liter)

10.6 Another method of expressing concentration is ppm.

$$ppm = mg/cu \times 24.45/M.W. \times 760/P \times T + 273/298$$

Where:

P = Pressure (mm Hg) of air sampled.

T = Temperature (°C) of air sampled.

24.45 = Molar volume (liter/mole) at 25° C and 760 mm Hg.

M.W. = Molecular weight (g/mole) of analyte.

760 = Standard pressure (mm Hg).

298 = Standard temperature (°K).

11. *References.*

11.1 White, L. D. et al., "A Convenient Optimized Method for the Analysis of Selected Solvent Vapors in the Industrial Atmosphere," *Amer. Ind. Hyg. Assoc. J., 31*:225 (1970).

11.2 Documentation of NIOSH Validation Tests, NIOSH Contract No. CDC-99-74-45.

11.3 Final Report, NIOSH Contract HSM-99-71-31, "Personal Sampler Pump for Charcoal Tubes," September 15, 1972.

NIOSH MODIFICATION OF NIOSH METHOD S-156

The NIOSH recommended method for low levels for acrylonitrile is a modification of method S-156. It differs in the following respects:

(1) Samples are desorbed using 1 ml of 1 percent acetone in CS_2 rather than methanol.

(2) The analytical column and conditions are:

Column: 20 percent SP-1000 on 80/100 Supelcoport 10 feet x ⅛ inch S.S.

Conditions:

Injector temperature: 200° C.
Detector temperature: 100° C.
Column temperature: 85° C.
Helium flow: 25 ml/min.
Air flow: 450 ml/min.
Hydrogen flow: 55 ml/min.

(3) A 2 μl injection of the desorbed analyte is used.

(4) A sampling rate of 100 ml/min is recommended.

OSHA LABORATORY MODIFICATION OF NIOSH METHOD S-156

Analyte: Acrylonitrile.

Matrix: Air.

Procedure: Adsorption on charcoal, desorption with methanol, GC.

1. *Principle of the Method* (Reference 1).

1.1 A known volume of air is drawn through a charcoal tube to trap the organic vapors present.

1.2 The charcoal in the tube is transferred to a small, stoppered sample vial, and the analyte is desorbed with methanol.

1.3 An aliquot of the desorbed sample is injected into a gas chromatograph.

1.4 The area of the resulting peak is determined and compared with areas obtained for standards.

2. *Advantages and disadvantages of the method.*

2.1 The sampling device is small, portable, and involves no liquids. Interferences are minimal, and most of those which do occur can be eliminated by altering chromatographic conditions. The tubes are analyzed by means of a quick, instrumental method.

2.2 This method may not be adequate for the simultaneous analysis of two or more substances.

2.3 The amount of sample which can be taken is limited by the number of milligrams that the tube will hold before overloading. When the sample value obtained for the backup section of the charcoal tube exceeds 25 percent of that found on the front section, the possibility of sample loss exists.

2.4 The precision of the method is limited by the reproducibility of the pressure drop across the tubes. This drop will affect the flow rate and cause the volume to be imprecise, because the pump is usually calibrated for one tube only.

3. *Apparatus.*

3.1 A calibrated personal sampling pump whose flow can be determined within ±5 percent at the recommended flow rate.

3.2 Charcoal tubes: Glass tube with both ends flame sealed, 7 cm long with a 6-mm O.D. and a 4-mm I.D., containing 2 sections of 20/40 mesh activated charcoal separated by a 2-mm portion of urethane foam. The activated charcoal is prepared from coconut shells and is fired at 600° C prior to packing. The absorbing section contains 100 mg of charcoal, the back-up section 50 mg. A 3-mm portion of urethane foam is placed between the outlet end of the tube and the back-up section. A plug of sililated glass wool is placed in front of the adsorbing section. The pressure drop across the tube must be less than one inch of mercury at a flow rate of 1 liter per minute.

3.3 Gas chromatograph equipped with a nitrogen phosphorus detector.

3.4 Column (10-ft x 1/8"-in stainless steel) packed with 100/120 Supelcoport coated with 10 percent SP 1000.

3.5 An electronic integrator or some other suitable method for measuring peak areas.

3.6 Two-milliliter sample vials with Teflon-lined caps.

3.7 Microliter syringes: 10-microliter, and other convenient sizes for making standards.

3.8 Pipets: 1.0-ml delivery pipets.

3.9 Volumetric flasks: convenient sizes for making standard solutions.

4. *Reagents.*

4.1 Chromatographic quality methanol.

4.2 Acrylonitrile, reagent grade.

4.3 Filtered compressed air.

4.4 Purified hydrogen.

4.5 Purified helium.

5. *Procedure.*

5.1 Cleaning of equipment. All glassware used for the laboratory analysis should be properly cleaned and free of organics which could interfere in the analysis.

5.2 Calibration of personal pumps. Each pump must be calibrated with a representative charcoal tube in the line.

5.3 Collection and shipping of samples.

5.3.1 Immediately before sampling, break the ends of the tube to provide an opening at least one-half the internal diameter of the tube (2 mm).

5.3.2 The smaller section of the charcoal is used as the backup and should be placed nearest the sampling pump.

5.3.3 The charcoal should be placed in a vertical position during sampling to minimize channeling through the charcoal.

5.3.4 Air being sampled should not be passed through any hose or tubing before entering the charcoal tube.

5.3.5 A sample size of 20 liters is recommended. Sample at a flow rate of approximately 0.2 liters per minute. The flow rate should be known with an accuracy of at least $\pm^5$ percent.

5.3.6 The temperature and pressure of the atmosphere being sampled should be recorded.

5.3.7 The charcoal tubes should be capped with the supplied plastic caps immediately after sampling. Rubber caps should not be used.

5.3.8 Submit at least one blank tube (a charcoal tube subjected to the same handling procedures, without having any air drawn through it) with each set of samples.

5.3.9 Take necessary shipping and packing precautions to minimize breakage of samples.

5.4 Analysis of samples.

5.4.1 Preparation of samples. In preparation for analysis, each charcoal tube is scored with a file in front of the first section of charcoal and broken open. The glass wool is removed and discarded. The charcoal in the first (larger) section is transferred to a 2-ml vial. The separating section of foam is removed and discarded; the section is transferred to another capped vial. These two sections are analyzed separately.

5.4.2 Desorption of samples. Prior to analysis, 1.0 ml of methanol is pipetted into each sample container. Desorption should be done for 30 minutes in an ultrasonic bath. The sample vials are recapped as soon as the solvent is added.

5.4.3 GC conditions. The typical operating conditions for the gas chromatograph are:

1. 30 ml/min (60 psig) helium carrier gas flow.

2. 3.0 ml/min (30 psig) hydrogen gas flow to detector.

3. 50 ml/min (60 psig) air flow to detector.

4. 200° C injector temperature.

5. 200° C dejector temperature.

6. 100° C column temperature.

5.4.4 Injection. Solvent flush technique or equivalent.

5.4.5 Measurement of area. The area of the sample peak is measured by an electronic integator or some other suitable form of area measurement, and preliminary results are read from a standard curve prepared as discussd below.

5.5 Determination of desorption efficiency.

5.5.1 Importance of determination. The desorption efficiency of a particular compound can vary from one laboratory to another and also from one batch of charcoal to another. Thus, it is necesary to determine, at least once, the percentage of the specific compound that is removed in the desorption process, provided the same batch of charcoal is used.

5.5.2 Procedure for determining desorption efficiency. The reference portion of the charcoal tube is removed. To the remaining portion, amounts representing 0.5X, 1X, and 2X (X represents TLV) based on a 20 l air sample are injected onto several tubes at each level. Dilutions of acrylonitrile with methanol are made to allow injection of measurable quantities. These tubes are then allowed to equilibrate at least overnight. Following equilibration they are analyzed following the same procedure as the samples. A curve of the desorption efficiency

amt recovered/amt added

is plotted versus amount of analyte found. This curve is used to correct for adsorption losses.

6. *Calibration and standards.*

A series of standards, varying in concentration over the range of interest, is prepared and analyzed under the same GC conditions and during the same time period as the unknown samples. Curves are prepared by plotting concentration versus peak area.

NOTE—Since no internal standard is used in the method, standard solutions must be analyzed at the same time that the sample analysis is done. This will minimize the effect of known day-to-day variations and variations during the same day of the NPD response. Multiple injections are necessary.

7. *Calculations.*

Read the weight, corresponding to each peak area from the standard curve, correct for the blank, correct for the desorption efficiency, and make necessary air volume corrections.

8. *Reference.* NIOSH Method S-156.

(Secs. 4, 6, 8, 84 Stat. 1592, 1593, 1596, 1599 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 8-76 (41 FR 25059); 29 CFR Part 1911.)

[FR Doc. 78-27880 Filed 9-29-78; 8:45 am]

Public Papers of the Presidents of the United States

Annual volumes containing the public messages and statements, news conferences, and other selected papers released by the White House.

Volumes for the following years are now available:

HERBERT HOOVER

1929	$13.30	1931	$14.00
1930	$16.00	1932–33	$17.25

HARRY S. TRUMAN

1945	$11.75	1949	$11.80
1946	$10.80	1950	$13.85
1947	$11.15	1951	$12.65
1948	$15.95	1952–53	$18.45

DWIGHT D. EISENHOWER

1953	$14.60	1957	$14.50
1954	$17.20	1958	$14.70
1955	$14.50	1959	$14.95
1956	$17.30	1960–61	$16.85

JOHN F. KENNEDY

1961	$14.35	1962	$15.55
		1963	$15.35

LYNDON B. JOHNSON

1963–64 (Book I)	$15.00	1966 (Book II)	$14.35
1963–64 (Book II)	$15.25	1967 (Book I)	$12.85
1965 (Book I)	$12.25	1967 (Book II)	$11.60
1965 (Book II)	$12.35	1968–69 (Book I)	$14.05
1966 (Book I)	$13.30	1968–69 (Book II)	$12.80

RICHARD NIXON

1969	$17.15	1972	$18.55
1970	$18.30	1973	$16.50
1971	$18.85	1974	$12.30

GERALD R. FORD

1974	$16.00	1975 (Book I)	$13.50
		1975 (Book II)	$13.75

Published by Office of the Federal Register, National Archives and Records Service, General Services Administration

Order from Superintendent of Documents, U.S. Government Printing Office Washington, D.C. 20402